

US3312249 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:57:13

All time stamps listed in this document are displayed in GMT



US3312249

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

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Participant ID

US3312249

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[mRNA-1273-P301 Completion Guidelines](#)

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US3312249

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN



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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Date of Informed Consent ( <i>dd MMM yyyy</i> )	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1



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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Were any significant conditions reported?

Yes ☒  
No ☐



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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	OSTEOARTHTITIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	RIGHT RADIAL STYLOIDECTOMY
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	RIGHT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013



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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	LEFT HIP ARTHROPLASTY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015



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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	RIGHT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020



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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	SMALL BOWEL BACTERIAL OVERGROWTH
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	RIGHT RADIAL STYLOID IMPINGEMENT
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010



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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	RIGHT ROTATOR CUFF TEAR
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013



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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	RIGHT ROTATOR CUFF TEAR
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020



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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Condition	RADIOSCAPHOIDAL IMPINGEMENT
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:41 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:41
Height ( <i>xxx.x</i> )	72 in
Weight ( <i>xxx.x</i> )	158 lb
BMI ( <i>xxx.x</i> )	21.47346 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:23:52

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:23:52

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**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☐ No ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:23:52

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	True
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 187982

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☐   
 >=18 and <65 years and at risk ☐   
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Height	ND - Not Done
Weight	ND - Not Done



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	14:41 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:41
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	16:17 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:17
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:23:52

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Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

What was the treatment time? (00:00-23:59) 15:45 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 15:45

Which arm was used to give treatment? Left Arm ☒  
Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	24 AUG 2020
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Collection time (00:00-23:59)	15:09 (24 HR)
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Collection date and time (derived)	24 AUG 2020 15:09
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:05	24 AUG 2020 15:05
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

24 AUG 2020 16:18

PC Open Date & Time

24 AUG 2020 16:05

PC Close Date & Time

24 AUG 2020 18:35



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	24 AUG 2020 20:14
PC Open Date & Time	24 AUG 2020 19:30
PC Close Date & Time	25 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

25 AUG 2020 19:57

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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**TIMEPOINT**

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

26 AUG 2020 20:09

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

27 AUG 2020 20:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

28 AUG 2020 19:59

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

29 AUG 2020 19:32

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

30 AUG 2020 19:33

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 16:19

PC Open Date & Time

24 AUG 2020 16:05

PC Close Date & Time

24 AUG 2020 18:35



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 20:15

PC Open Date & Time

24 AUG 2020 19:30

PC Close Date & Time

25 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

60

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 19:58

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

65

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 20:10

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

55

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 20:02

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:00

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 19:32

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 19:33

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 16:21
PC Open Date & Time	24 AUG 2020 16:05
PC Close Date & Time	24 AUG 2020 18:35



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 20:16
PC Open Date & Time	24 AUG 2020 19:30
PC Close Date & Time	25 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:59
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:11
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:01
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

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EAB) (1725)

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US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:33
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:34
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3312249

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3312249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:08
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG



US3312249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:25
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



US3312249

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



US3312249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 SEP 2020

What was the treatment time? (00:00-23:59) 10:54 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 10:54

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR



US3312249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	10:17 (24 HR)
Collection date and time (derived)	28 SEP 2020 10:17



US3312249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:04	28 SEP 2020 10:04
Nasopharyngeal Swab 2	No		



US3312249

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

28 SEP 2020 11:26

PC Open Date & Time

28 SEP 2020 11:14

PC Close Date & Time

28 SEP 2020 13:44



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	28 SEP 2020 19:59
PC Open Date & Time	28 SEP 2020 14:39
PC Close Date & Time	29 SEP 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 SEP 2020 19:39

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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**TIMEPOINT**

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.5 °F

---

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

---

Please confirm reason for pain or fever medication (may select more than one):

---

PC Time Stamp

30 SEP 2020 20:03

---

PC Open Date & Time

30 SEP 2020 12:00

---

PC Close Date & Time

01 OCT 2020 11:59

---



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

01 OCT 2020 19:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

02 OCT 2020 19:41

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False
PC Time Stamp	03 OCT 2020 19:26
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

04 OCT 2020 20:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 11:27

PC Open Date & Time

28 SEP 2020 11:14

PC Close Date & Time

28 SEP 2020 13:44



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 20:00

PC Open Date & Time

28 SEP 2020 14:39

PC Close Date & Time

29 SEP 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

80

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 19:40

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

120

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 20:05

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

150

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 19:29

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

150

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 19:42

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

75

Measure the largest size across any injection site redness with the  
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 19:28

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 20:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 11:28
PC Open Date & Time	28 SEP 2020 11:14
PC Close Date & Time	28 SEP 2020 13:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 20:01
PC Open Date & Time	28 SEP 2020 14:39
PC Close Date & Time	29 SEP 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:41
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 20:07
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒



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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 19:30
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 19:43
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

No ☒



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:29
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?

No ☒



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:05
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 05 OCT 2020 19:20

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 05 OCT 2020 19:20

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:57:13

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 19:21
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59



US3312249

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:57:13

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59



US3312249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3312249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:20
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3312249

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



US3312249

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	08:40 (24 HR)
Collection date and time (derived)	23 OCT 2020 08:40



US3312249

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:23:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 64

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 OCT 2020 13:10:22

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59



US3312249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

02 NOV 2020 19:44:39

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59



US3312249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 11:58:21
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 07:00:49
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 07:13:36
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

02 DEC 2020 07:44:15

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

09 DEC 2020 12:48:42

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 DEC 2020 09:52:28

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 124

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

23 DEC 2020 10:05:54

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

30 DEC 2020 10:23:16

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	06 JAN 2021 09:02:23
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 145

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

13 JAN 2021 11:08:41

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

21 JAN 2021 10:59:23

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 08:25:58
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 09:56:58
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 FEB 2021 19:24:20

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 07:21:12
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 FEB 2021 14:36:56

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 13:02:21
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 201

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 MAR 2021 07:40:12

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 MAR 2021 07:30:03

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 MAR 2021 07:32:58

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

31 MAR 2021 16:15:55

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

07 APR 2021 09:21:39

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 236

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 APR 2021 09:11:53

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

22 APR 2021 14:12:15

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

28 APR 2021 15:06:43

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 348

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59
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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	17 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	21 NOV 2021 23:59
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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JAN 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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23 JAN 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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30 JAN 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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06 FEB 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

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Date and time of submission

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09 FEB 2022 00:01

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13 FEB 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

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Date and time of submission

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

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Date and time of submission

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23 FEB 2022 00:01

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27 FEB 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:57:13**

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Date and time of submission

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

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Date and time of submission

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09 MAR 2022 00:01

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13 MAR 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

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<a href="#">Patient Cloud Open Date &amp; Time</a>	16 MAR 2022 00:01
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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



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Date and time of submission

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23 MAR 2022 00:01

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27 MAR 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 APR 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 MAY 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUN 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUN 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUL 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 OCT 2022 23:59



US3312249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59



**US3312249**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 16:57:13**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 15:12:38



US3312249

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 JAN 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 FEB 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312249

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312249

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	30 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3312249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_



US3312249

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



US3312249

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	09:16 (24 HR)
Collection date and time (derived)	30 MAR 2021 09:16



US3312249

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3312249**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3312249**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3312249**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:57:13**

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>



**US3312249**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:57:13**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3312249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	02 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3312249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:33:43

Generated On: 09 Jun 2021 16:57:13

Date of updated informed consent (dd MMM yyyy) 02 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 02 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_



US3312249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:33:43

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	02 FEB 2021
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Collection time (00:00-23:59)	09:07 (24 HR)
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Collection date and time (derived)	02 FEB 2021 09:07
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US3312249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:33:43

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00 - 23:59)	09:06
Collection Date and Time (derived)	02 FEB 2021 09:06



US3312249

Folder: Unscheduled 24 Aug 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Visit Date	24 AUG 2020
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Please check all assessments that apply for this visit

Physical Exam	False
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Vital Signs	True
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Immunogenicity Assessment	False
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Pregnancy Test	False
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US3312249

Folder: Unscheduled 24 Aug 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:33:44

Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:24 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:24
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3312249

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:53:07

Generated On: 09 Jun 2021 16:57:13

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3312249

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

AEID

Adverse event

LEFT INJECTION SITE RASH

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

01 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____



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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

AEID

Adverse event

INTESTINAL INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:58:42

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

AEID	USA-US300-2021-MRNA-1273-P30 1000004
Adverse event	LEFT LOWER EXTREMITY DEEP VEIN THROMBOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:58:42

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	



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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:58:42

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66 YEAR OLD MAN DEVELOPED  
LEFT CALF PAIN WITH  
MINIMAL TO NO SWELLING  
02JAN2021 FOR WHICH HE  
VISITED ER. ULTRASOUND  
REVEALED DEEP VENOUS  
THROMBOSIS. SUBJECT WAS  
DISCHARGED TO HOME SAME  
DAY ON XARELTO AND HE  
BELIEVES HE RECEIVED NO  
OTHER MEDS. HE REPORTS  
TRAVELLING BOTH BY  
AUTOMOBILE AND PLANE  
SEVERAL TIMES BACK AND  
FORTH TO FLORIDA FROM  
KANSAS CITY OVER LAST FEW  
MONTHS AND INCREASED  
SEDENTARY LIFESTYLE DUE  
TO RECENT CHANGE FROM  
HOUSE TO APARTMENT. THE  
ER ADVISED HIM THAT IN HIS  
CASE THERE WERE NO TRAVEL  
CONCERNS OR RESTRICTIONS  
RELATED TO THE CLOT, AND  
THAT HE COULD RESUME  
NORMAL ACTIVITY INCLUDING  
MODERATE EXERCISE  
IMMEDIATELY. HE WAS  
ADVISED BY ER AND NOW BY  
ME TO IMMEDIATELY SEEK  
MEDICAL ATTENTION SHOULD  
ANY SYMPTOMS OF PE  
APPEAR. HE SOUNDS WELL  
OVER THE PHONE, REPORTS  
THAT HE IS TOLERATING



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Folder: Adverse Events

Form: Adverse Events (5)

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EXERCISE NORMALLY, AND THAT PAIN IS IMPROVED. HE DENIES SWELLING. WILL GET MED RECORDS.F/U 22JAN2021 MR CONSISTENT WITH ORIGINAL REPORT THAT AFTER APPROXIMATELY A DAY OR SO OF LEFT CALF PAIN SUBJECT VISITED ER ON 04JAN21 WITH CONCERN FOR DVT. HE WAS CORRECT; ULTRASOUND REVEALED OCCLUSIVE THROMBUS WITHIN THE DISTAL POPLITEAL AND A POSTERIOR TIBIAL VEIN AND NON-OCCLUSIVE THROMBUS WITHIN THE PROXIMAL POPLITEAL, A POSTERIOR TIBIAL, AND THE PERONEAL VEINS. THERE WAS NO SWELLING OF THE EXTREMITY, NO SHORTNESS OF AIR, AND NO SYMPTOMS OF COVID-19. PT, PTT, INR WERE WNL. COVID TEST WAS NOT DONE. SUBJECT HAS HISTORY OF HTN AND BP WAS IN THE 180'S AND THEN 170'S SYSTOLIC. HE WAS STARTED ON XARELTO 15MG PO BID AND DISCHARGED TO HOME. ON PHONE CALL THIS AM 22JAN21 SUBJECT SOUNDS WELL AND VIBRANT, REPORTS HE FEELS WELL ON XARELTO,



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Folder: Adverse Events

Form: Adverse Events (5)

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AND DENIES SHORTNESS OF  
AIR AND LOWER EXTREMITY  
SWELLING OR DISCOMFORT.  
HE HAS NOT HAD A RECENT  
COVID TEST AND IS OUT OF  
STATE 04/08/21 F/U: US DONE  
04/01/21-NO EVIDENCE OF  
CLOT, CONTINUES XARELTO  
PROPHYLACTICALLY 3 MORE  
MOS.AE CLOSED

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 21:33:43

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:33:42

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Name of Medication PRAVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:33:42

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:33:42

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Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication PROPRANOLOL ER

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 80

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:33:42

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:33:42

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Name of Medication ACETYLSALICYLIC ACID

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:33:42

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Name of Medication COENZYME Q10

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication PROSTATE PLUS

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication FLEX 1 (GLUCOSAMINE  
750MG/CHONDROITIN SULFATE  
400MG/  
METHYLSUFONYLMETHANE  
375MG)

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication SULFAMETHOXAZOLE/TRIMETHOPRIM

Prophylaxis Yes ☐  
No ☒

Indication INTestinal Infection

Dose per administration 800/160

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication LINACLOTIDE

Prophylaxis Yes ☐  
No ☒

Indication SMALL BOWEL BACTERIAL  
OVERGROWTH

Dose per administration 145

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE ACHES/JOINT ACHES

Dose per administration 400

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE ACHES/JOINT ACHES

Dose per administration 400

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 03 OCT 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication SEASONAL INFLUENZA  
VACCINE

Prophylaxis Yes ☒  
No ☐

Indication SEASONAL INFLUENZA  
VACCINE

Dose per administration 0.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 21:33:42

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	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication LEFT CALF VENOUS  
THROMBOSIS

Dose per administration 15

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication LEFT CALF VENOUS  
THROMBOSIS

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 21:33:42

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 21:33:43

Generated On: 09 Jun 2021 16:57:13

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---



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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:57:13

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify



US3312249

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:57:13

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/JAN/2021 13:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/JAN/2021 19:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/APR/2021 12:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 15:58:42

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US300-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/APR/2021 09:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3312249 (Prod: Johnson County Clin-Trials)



**US3312249**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:57:13**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'US3312249'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 19:14:30



**US3312249**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:48:55



**US3312249**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 19:14:31



**US3312249**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	24 Aug 2020 20:48:55



**US3312249**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'SCRN'	System	24 Aug 2020 20:48:55



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 19:14:32



US3312249

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User closed query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 11:22:12
Query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:55
User entered '65'	Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49
User opened query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 07:01:23



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'YEARS'	System	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '65'	System	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Male (M)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	03 Sep 2020 16:45:49



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 Aug 2020'	Christa Estrada (b) (4)	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Aug 2020'	System	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2020'	System	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:06



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 19:14:31



**US3312249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:57:13**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'I'	System	24 Aug 2020 20:49:11



**US3312249**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 16:57:13**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:11



**US3312249**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 16:57:13**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:13:58



US3312249

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:15:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:15:46
Data point term sent to Coder	System	10 Sep 2020 00:15:11
User entered 'HYPERTENSION'	Karol Moore (b) (4)	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2017'	System	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2017'	System	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	10 Sep 2020 00:14:13



**US3312249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	10 Sep 2020 00:14:13



US3312249

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:15:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:15:46
Data point term sent to Coder	System	10 Sep 2020 00:15:11
User entered 'HYPERLIPIDEMIA'	Karol Moore (b) (4)	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2000'	System	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2000'	System	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	10 Sep 2020 00:14:27



**US3312249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	10 Sep 2020 00:14:27



US3312249

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:15:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:15:46
Data point term sent to Coder	System	10 Sep 2020 00:15:11
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4)	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2000'	System	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2000'	System	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	10 Sep 2020 00:14:38



**US3312249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	10 Sep 2020 00:14:38



US3312249

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 08:04:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 08:04:35
Data point term sent to Coder	System	10 Sep 2020 00:15:09
User entered 'OSTEOARTHTITIS'	Karol Moore (b) (4)	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2010'	System	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2010'	System	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	10 Sep 2020 00:14:52



**US3312249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	10 Sep 2020 00:14:52



US3312249

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 09:02:46
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'associated condition added to line 10' (Site from DM).	Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:09:53
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:43:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Ostectomy, LLT: Ostectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 10:31:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 10:31:50
Data point term sent to Coder	System	10 Sep 2020 00:16:12
User entered 'RIGHT RADIAL STYLOIDECTOMY'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2010'	System	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2010'	System	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2010'	System	10 Sep 2020 00:15:12



**US3312249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2010'	System	10 Sep 2020 00:15:12



US3312249

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 09:03:11
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'associated condition added to line 11' (Site from DM).	Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:10:12
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:43:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:16:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:16:47
Data point term sent to Coder	System	10 Sep 2020 00:16:14
User entered 'RIGHT ROTATOR CUFF REPAIR'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2013'	System	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2013'	System	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2013'	System	10 Sep 2020 00:15:35



**US3312249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2013'	System	10 Sep 2020 00:15:35



US3312249

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 09:03:31
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'associated condition added to line 12' (Site from DM).	Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:10:24
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:44:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:16:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:16:47
Data point term sent to Coder	System	10 Sep 2020 00:16:12
User entered 'LEFT HIP ARTHROPLASTY'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2015'	System	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2015'	System	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2015'	System	10 Sep 2020 00:15:57



**US3312249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2015'	System	10 Sep 2020 00:15:57



US3312249

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 09:03:55
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'associated condition added to line 12' (Site from DM).	Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:10:51
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:44:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:17:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:17:47
Data point term sent to Coder	System	10 Sep 2020 00:17:14
User entered 'RIGHT ROTATOR CUFF REPAIR'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN Apr 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN Apr 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Apr 2020'	System	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2020'	System	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Apr 2020'	System	10 Sep 2020 00:16:33



**US3312249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2020'	System	10 Sep 2020 00:16:33



US3312249

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Gastrointestinal bacterial overgrowth, LLT: Small intestinal bacterial overgrowth - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 05:10:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 05:10:15
Data point term sent to Coder	System	18 Oct 2020 21:58:08
User entered 'small bowel bacterial overgrowth'	Karol Moore (b) (4)	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'un Jan 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2020'	System	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2020'	System	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	18 Oct 2020 21:57:42



**US3312249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered empty.	System	18 Oct 2020 21:57:42



US3312249

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tenosynovitis stenans, LLT: Radial styloid tenosynovitis - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 14:29:42
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 14:29:42
Data point term sent to Coder	System	25 Oct 2020 21:08:28
User entered 'right radial styloid impingement'	Karol Moore (b) (4)	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'un UNK 2009'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2009'	System	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2009'	System	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2010'	System	25 Oct 2020 21:08:24



**US3312249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2010'	System	25 Oct 2020 21:08:24



US3312249

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	25 Oct 2020 21:10:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Oct 2020 21:10:29
Data point term sent to Coder	System	25 Oct 2020 21:09:28
User entered 'right rotator cuff tear'	Karol Moore (b) (4)	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'un UNK 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'un UNK 2013'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2013'	System	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2013'	System	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2013'	System	25 Oct 2020 21:08:50



**US3312249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2013'	System	25 Oct 2020 21:08:50



US3312249

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	25 Oct 2020 21:10:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Oct 2020 21:10:29
Data point term sent to Coder	System	25 Oct 2020 21:09:30
User entered 'right rotator cuff tear'	Karol Moore (b) (4)	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'un Jan 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'un Apr 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2020'	System	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2020'	System	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Apr 2020'	System	25 Oct 2020 21:09:27



**US3312249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2020'	System	25 Oct 2020 21:09:27



US3312249

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Wrist injury - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 10:09:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 10:09:40
Data point term sent to Coder	System	13 Nov 2020 15:47:26
User entered 'RADIOSCAPHOIDAL IMPINGEMENT'	Karol Moore (b) (4)	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2005'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'UN UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2005'	System	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2005'	System	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'Jan 2010'	System	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '2010'	System	13 Nov 2020 15:46:34



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:05



US3312249

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	10 Sep 2020 00:17:15
User entered '24 Aug 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	10 Sep 2020 00:17:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	10 Sep 2020 00:17:05
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:17:05
	(b) (4)	



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '14:41'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '24 Aug 2020 14:41'	System	10 Sep 2020 00:17:15
User entered empty.	System	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '72' in	(b) (4)	10 Sep 2020 00:17:05
DataPoint set to visible.	Karol Moore (b) (4)	24 Aug 2020 20:49:11
	(b) (4)	
	System	



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '158' lb	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:17:05
DataPoint set to visible.	(b) (4) System	24 Aug 2020 20:49:11



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered '21.47346'	System	10 Sep 2020 00:17:05
DataPoint set to visible.	System	24 Aug 2020 20:49:11



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'kg/m2'	System	10 Sep 2020 00:17:05
DataPoint set to visible.	System	24 Aug 2020 20:49:11



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'bpm'	System	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'breaths/min'	System	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'mmHg'	System	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User entered 'mmHg'	System	10 Sep 2020 00:17:05



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20



**US3312249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20



**US3312249**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:25



**US3312249**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:25



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:17:47



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



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Folder: Screening

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



US3312249

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:17:47



**US3312249**

**Folder: Screening**

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**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



**US3312249**

**Folder: Screening**

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



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**Folder: Screening**

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**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



**US3312249**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:57:13**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



**US3312249**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:08:20
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:17:47



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:21



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 Aug 2020'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:21



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	24 Aug 2020 20:49:21



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'VISIT1'	System	24 Aug 2020 20:49:21



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 20:24:28



US3312249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '187982'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 20:24:28



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 20:24:28



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:57:13**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	Christa Estrada (b) (4)	24 Aug 2020 20:49:31



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:57:13**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	Christa Estrada (b) (4)	24 Aug 2020 20:49:31



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:57:13**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:31



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:57:13**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:31



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:57:13**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:31



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:57:13**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 21:59:52
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:40:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:43:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:57:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:57:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:57:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:57:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:18:53



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	10 Sep 2020 00:18:53
	(b) (4)	



US3312249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '14:41'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered '24 Aug 2020 14:41'	System	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '97.9' F	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '64'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'bpm'	System	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'breaths/min'	System	10 Sep 2020 00:18:53



US3312249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '138'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'mmHg'	System	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '90'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



US3312249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'mmHg'	System	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:57:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:57:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:18:53



US3312249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '16:17'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered '24 Aug 2020 16:17'	System	10 Sep 2020 00:18:53



US3312249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '97.7' F	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



US3312249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '61'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'bpm'	System	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'breaths/min'	System	10 Sep 2020 00:18:53



US3312249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '147'	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:18:53



US3312249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'mmHg'	System	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '92'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'mmHg'	System	10 Sep 2020 00:18:53



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:54



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:54



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:57



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:57



US3312249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	Christa Estrada (b) (4)	24 Aug 2020 20:49:57



US3312249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 20:49:57



US3312249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 Aug 2020'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:57



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '15:45'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:57



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered '24 Aug 2020 15:45'	System	24 Aug 2020 20:49:57



US3312249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 20:49:57



US3312249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'ONCE'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:14



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:14



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '15:09'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:14



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered '24 Aug 2020 15:09'	System	10 Sep 2020 00:20:14



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 16:57:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '15:05'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered '24 Aug 2020 15:05'	System	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered empty.	System	10 Sep 2020 00:20:26



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:29



**US3312249**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered '1'	System	10 Sep 2020 00:20:29



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:16:43', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bf05a54-8f06-4c1d-8c08-0779ee2f52a7'	System	24 Aug 2020 21:18:08
User entered 'Yes (Y)'	System	24 Aug 2020 21:18:08



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:16:52', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bf05a54-8f06-4c1d-8c08-0779ee2f52a7' User entered '97.7'	System	24 Aug 2020 21:18:08
	System	24 Aug 2020 21:18:08



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:17:55', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bf05a54-8f06-4c1d-8c08-0779ee2f52a7'	System	24 Aug 2020 21:18:08
User entered 'No (N)'	System	24 Aug 2020 21:18:08



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:18:05', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bf05a54-8f06-4c1d-8c08-0779ee2f52a7'	System	24 Aug 2020 21:18:08
User entered '24 Aug 2020 16:18'	System	24 Aug 2020 21:18:08



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 16:05'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 18:35'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:14:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c746960b-6c9f-48e7-b192-70895c1e976b' User entered 'Yes (Y)'	System	25 Aug 2020 01:14:34
	System	25 Aug 2020 01:14:34



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:14:11', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c746960b-6c9f-48e7-b192-70895c1e976b' User entered '96.8'	System	25 Aug 2020 01:14:34
	System	25 Aug 2020 01:14:34



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:14:17', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c746960b-6c9f-48e7-b192-70895c1e976b' User entered 'No (N)'	System	25 Aug 2020 01:14:34
	System	25 Aug 2020 01:14:34



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:14:29', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c746960b-6c9f-48e7-b192-70895c1e976b' User entered '24 Aug 2020 20:14'	System	25 Aug 2020 01:14:34
	System	25 Aug 2020 01:14:34



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 19:30'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 2'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:56:40', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '31abf5bc-9291-48e3-98bd-93c0daeb7d97'	System	26 Aug 2020 00:57:03
User entered 'Yes (Y)'	System	26 Aug 2020 00:57:03



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:56:47', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '31abf5bc-9291-48e3-98bd-93c0daeb7d97'	System	26 Aug 2020 00:57:03
User entered '98.4'	System	26 Aug 2020 00:57:03



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:56:51', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '31abf5bc-9291-48e3-98bd-93c0daeb7d97'	System	26 Aug 2020 00:57:03
User entered 'No (N)'	System	26 Aug 2020 00:57:03



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:57:01', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '31abf5bc-9291-48e3-98bd-93c0daeb7d97'	System	26 Aug 2020 00:57:03
User entered '25 Aug 2020 19:57'	System	26 Aug 2020 00:57:03



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 3'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:08:56', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4c6bffe4-2a60-495e-954f-650db23c65ca' User entered 'Yes (Y)'	System	27 Aug 2020 01:09:25
	System	27 Aug 2020 01:09:25



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:09:05', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4c6bffe4-2a60-495e-954f-650db23c65ca' User entered '97.5'	System	27 Aug 2020 01:09:25
	System	27 Aug 2020 01:09:25



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:09:10', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4c6bffe4-2a60-495e-954f-650db23c65ca'	System	27 Aug 2020 01:09:25
User entered 'No (N)'	System	27 Aug 2020 01:09:25



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:09:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4c6bffe4-2a60-495e-954f-650db23c65ca' User entered '26 Aug 2020 20:09'	System	27 Aug 2020 01:09:25
	System	27 Aug 2020 01:09:25



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 4'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:00:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '685cbbab-8e13-4e6b-a815-1926ace862c3' User entered 'Yes (Y)'	System	28 Aug 2020 01:00:45
	System	28 Aug 2020 01:00:45



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:00:28', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '685cbbab-8e13-4e6b-a815-1926ace862c3' User entered '97.1'	System	28 Aug 2020 01:00:45
	System	28 Aug 2020 01:00:45



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:00:34', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '685cbbab-8e13-4e6b-a815-1926ace862c3' User entered 'No (N)'	System	28 Aug 2020 01:00:45
	System	28 Aug 2020 01:00:45



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:00:43', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '685cbbab-8e13-4e6b-a815-1926ace862c3' User entered '27 Aug 2020 20:00'	System	28 Aug 2020 01:00:45
	System	28 Aug 2020 01:00:45



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 5'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T19:59:14', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7e389451-edcc-493d-92e8-e92bb15ec87b' User entered 'Yes (Y)'	System	29 Aug 2020 00:59:38
	System	29 Aug 2020 00:59:38



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T19:59:23', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7e389451-edcc-493d-92e8-e92bb15ec87b' User entered '97.1'	System	29 Aug 2020 00:59:38
	System	29 Aug 2020 00:59:38



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T19:59:26', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7e389451-edcc-493d-92e8-e92bb15ec87b'	System	29 Aug 2020 00:59:38
User entered 'No (N)'	System	29 Aug 2020 00:59:38



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T19:59:33', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7e389451-edcc-493d-92e8-e92bb15ec87b' User entered '28 Aug 2020 19:59'	System	29 Aug 2020 00:59:38
	System	29 Aug 2020 00:59:38



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 6'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:31:43', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b6e9bea4-6f0f-44c9-8b31-44526b64787a' User entered 'Yes (Y)'	System	30 Aug 2020 00:32:14
	System	30 Aug 2020 00:32:14



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:31:53', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b6e9bea4-6f0f-44c9-8b31-44526b64787a' User entered '97.1'	System	30 Aug 2020 00:32:14
	System	30 Aug 2020 00:32:14



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b6e9bea4-6f0f-44c9-8b31-44526b64787a' User entered 'No (N)'	System	30 Aug 2020 00:32:14
	System	30 Aug 2020 00:32:14



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:10', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b6e9bea4-6f0f-44c9-8b31-44526b64787a' User entered '29 Aug 2020 19:32'	System	30 Aug 2020 00:32:14
	System	30 Aug 2020 00:32:14



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 7'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:32:46', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '40518a4f-ceaa-4045-a90e-579ff23426df' User entered 'Yes (Y)'	System	31 Aug 2020 00:37:17
	System	31 Aug 2020 00:37:17



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:32:52', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '40518a4f-ceaa-4045-a90e-579ff23426df' User entered '97.1'	System	31 Aug 2020 00:37:17
	System	31 Aug 2020 00:37:17



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:32:56', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '40518a4f-ceaa-4045-a90e-579ff23426df' User entered 'No (N)'	System	31 Aug 2020 00:37:17
	System	31 Aug 2020 00:37:17



US3312249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:04', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '40518a4f-ceaa-4045-a90e-579ff23426df' User entered '30 Aug 2020 19:33'	System	31 Aug 2020 00:37:17
	System	31 Aug 2020 00:37:17



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:18:50', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b0cf3fa8-2bbe-4d18-871f-099a2cc23acb' User entered 'None (1)'	System	24 Aug 2020 21:19:31
	System	24 Aug 2020 21:19:31



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:19:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b0cf3fa8-2bbe-4d18-871f-099a2cc23acb' User entered 'No (N)'	System	24 Aug 2020 21:19:31
	System	24 Aug 2020 21:19:31



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:19:08', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b0cf3fa8-2bbe-4d18-871f-099a2cc23acb' User entered 'No (N)'	System	24 Aug 2020 21:19:31
	System	24 Aug 2020 21:19:31



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:19:17', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b0cf3fa8-2bbe-4d18-871f-099a2cc23acb' User entered 'None (1)'	System	24 Aug 2020 21:19:31
	System	24 Aug 2020 21:19:31



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:19:28', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b0cf3fa8-2bbe-4d18-871f-099a2cc23acb' User entered '24 Aug 2020 16:19'	System	24 Aug 2020 21:19:31
	System	24 Aug 2020 21:19:31



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 16:05'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 18:35'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:14:42', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '670f47de-3f14-42d5-897d-5a348303d6db' User entered 'None (1)'	System	25 Aug 2020 01:15:22
	System	25 Aug 2020 01:15:22



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:14:49', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '670f47de-3f14-42d5-897d-5a348303d6db' User entered 'No (N)'	System	25 Aug 2020 01:15:22
	System	25 Aug 2020 01:15:22



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:14:54', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '670f47de-3f14-42d5-897d-5a348303d6db' User entered 'No (N)'	System	25 Aug 2020 01:15:22
	System	25 Aug 2020 01:15:22



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:15:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '670f47de-3f14-42d5-897d-5a348303d6db' User entered 'None (1)'	System	25 Aug 2020 01:15:22
	System	25 Aug 2020 01:15:22



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:15:19', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '670f47de-3f14-42d5-897d-5a348303d6db' User entered '24 Aug 2020 20:15'	System	25 Aug 2020 01:15:22
	System	25 Aug 2020 01:15:22



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 19:30'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 2'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:57:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd5f1a34e-5461-41ce-bcfd-8e48dd4c3fb4'	System	26 Aug 2020 00:58:43
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 00:58:43



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:57:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd5f1a34e-5461-41ce-bcfd-8e48dd4c3fb4'	System	26 Aug 2020 00:58:43
User entered 'Yes (Y)'	System	26 Aug 2020 00:58:43



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:57:32', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd5f1a34e-5461-41ce-bcfd-8e48dd4c3fb4' User entered '60'	System	26 Aug 2020 00:58:43
	System	26 Aug 2020 00:58:43



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:58:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd5f1a34e-5461-41ce-bcfd-8e48dd4c3fb4' User entered 'No (N)'	System	26 Aug 2020 00:58:43
	System	26 Aug 2020 00:58:43



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:58:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd5f1a34e-5461-41ce-bcfd-8e48dd4c3fb4' User entered 'None (1)'	System	26 Aug 2020 00:58:43
	System	26 Aug 2020 00:58:43



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:58:40', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd5f1a34e-5461-41ce-bcfd-8e48dd4c3fb4' User entered '25 Aug 2020 19:58'	System	26 Aug 2020 00:58:43
	System	26 Aug 2020 00:58:43



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 3'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:09:31', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8ded0253-3deb-4620-a680-9b8aa2ab6674'	System	27 Aug 2020 01:10:19
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 01:10:19



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:09:35', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8ded0253-3deb-4620-a680-9b8aa2ab6674'	System	27 Aug 2020 01:10:19
User entered 'Yes (Y)'	System	27 Aug 2020 01:10:19



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:09:46', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8ded0253-3deb-4620-a680-9b8aa2ab6674' User entered '65'	System	27 Aug 2020 01:10:19
	System	27 Aug 2020 01:10:19



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:09:52', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8ded0253-3deb-4620-a680-9b8aa2ab6674' User entered 'No (N)'	System	27 Aug 2020 01:10:19
	System	27 Aug 2020 01:10:19



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:09:59', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8ded0253-3deb-4620-a680-9b8aa2ab6674' User entered 'None (1)'	System	27 Aug 2020 01:10:19
	System	27 Aug 2020 01:10:19



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:10:16', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8ded0253-3deb-4620-a680-9b8aa2ab6674'	System	27 Aug 2020 01:10:19
User entered '26 Aug 2020 20:10'	System	27 Aug 2020 01:10:19



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 4'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:00:53', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2baa9d12-0054-4e2a-93c8-af127e803db0'	System	28 Aug 2020 01:02:44
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 01:02:44



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:01:55', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2baa9d12-0054-4e2a-93c8-af127e803db0' User entered 'Yes (Y)'	System	28 Aug 2020 01:02:44
	System	28 Aug 2020 01:02:44



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:02:06', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2baa9d12-0054-4e2a-93c8-af127e803db0' User entered '55'	System	28 Aug 2020 01:02:44
	System	28 Aug 2020 01:02:44



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:01:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2baa9d12-0054-4e2a-93c8-af127e803db0' User entered 'No (N)'	System	28 Aug 2020 01:02:44
	System	28 Aug 2020 01:02:44



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:01:14', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2baa9d12-0054-4e2a-93c8-af127e803db0' User entered 'None (1)'	System	28 Aug 2020 01:02:44
	System	28 Aug 2020 01:02:44



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:02:38', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2baa9d12-0054-4e2a-93c8-af127e803db0' User entered '27 Aug 2020 20:02'	System	28 Aug 2020 01:02:44
	System	28 Aug 2020 01:02:44



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 5'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:13', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8934bdae-a5e3-4368-bb31-a14a46b16944' User entered 'None (1)'	System	29 Aug 2020 01:00:46
	System	29 Aug 2020 01:00:46



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:19', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8934bdae-a5e3-4368-bb31-a14a46b16944'	System	29 Aug 2020 01:00:46
User entered 'No (N)'	System	29 Aug 2020 01:00:46



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:24', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8934bdae-a5e3-4368-bb31-a14a46b16944'	System	29 Aug 2020 01:00:46
User entered 'No (N)'	System	29 Aug 2020 01:00:46



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:29', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8934bdae-a5e3-4368-bb31-a14a46b16944' User entered 'None (1)'	System	29 Aug 2020 01:00:46
	System	29 Aug 2020 01:00:46



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:41', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8934bdae-a5e3-4368-bb31-a14a46b16944'	System	29 Aug 2020 01:00:46
User entered '28 Aug 2020 20:00'	System	29 Aug 2020 01:00:46



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 6'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:17', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'eec17ce2-e28b-485a-8d44-dbaa8566c3b9' User entered 'None (1)'	System	30 Aug 2020 00:32:50
	System	30 Aug 2020 00:32:50



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'eec17ce2-e28b-485a-8d44-dbaa8566c3b9' User entered 'No (N)'	System	30 Aug 2020 00:32:50
	System	30 Aug 2020 00:32:50



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:25', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'eec17ce2-e28b-485a-8d44-dbaa8566c3b9' User entered 'No (N)'	System	30 Aug 2020 00:32:50
	System	30 Aug 2020 00:32:50



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:34', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'eec17ce2-e28b-485a-8d44-dbaa8566c3b9' User entered 'None (1)'	System	30 Aug 2020 00:32:50
	System	30 Aug 2020 00:32:50



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:48', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'eec17ce2-e28b-485a-8d44-dbaa8566c3b9' User entered '29 Aug 2020 19:32'	System	30 Aug 2020 00:32:50
	System	30 Aug 2020 00:32:50



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 7'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:11', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c0dc4112-8b34-40dd-83ab-2d32ba170dcc' User entered 'None (1)'	System	31 Aug 2020 00:38:02
	System	31 Aug 2020 00:38:02



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:14', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c0dc4112-8b34-40dd-83ab-2d32ba170dcc'	System	31 Aug 2020 00:38:02
User entered 'No (N)'	System	31 Aug 2020 00:38:02



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:18', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c0dc4112-8b34-40dd-83ab-2d32ba170dcc' User entered 'No (N)'	System	31 Aug 2020 00:38:02
	System	31 Aug 2020 00:38:02



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:23', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c0dc4112-8b34-40dd-83ab-2d32ba170dcc'	System	31 Aug 2020 00:38:02
User entered 'None (1)'	System	31 Aug 2020 00:38:02



US3312249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:31', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c0dc4112-8b34-40dd-83ab-2d32ba170dcc' User entered '30 Aug 2020 19:33'	System	31 Aug 2020 00:38:02
	System	31 Aug 2020 00:38:02



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:19:55', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ec96d440-b3f7-4534-add7-7aa202dc21b1' User entered 'None (0)'	System	24 Aug 2020 21:21:07
	System	24 Aug 2020 21:21:07



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:20:04', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ec96d440-b3f7-4534-add7-7aa202dc21b1' User entered 'None (0)'	System	24 Aug 2020 21:21:07
	System	24 Aug 2020 21:21:07



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:20:16', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ec96d440-b3f7-4534-add7-7aa202dc21b1' User entered 'None (0)'	System	24 Aug 2020 21:21:07
	System	24 Aug 2020 21:21:07



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:20:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ec96d440-b3f7-4534-add7-7aa202dc21b1' User entered 'None (0)'	System	24 Aug 2020 21:21:07
	System	24 Aug 2020 21:21:07



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:20:31', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ec96d440-b3f7-4534-add7-7aa202dc21b1' User entered 'None (0)'	System	24 Aug 2020 21:21:07
	System	24 Aug 2020 21:21:07



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:20:36', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ec96d440-b3f7-4534-add7-7aa202dc21b1' User entered 'None (0)'	System	24 Aug 2020 21:21:07
	System	24 Aug 2020 21:21:07



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:20:49', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ec96d440-b3f7-4534-add7-7aa202dc21b1'	System	24 Aug 2020 21:21:07
User entered 'No (N)'	System	24 Aug 2020 21:21:07



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T16:21:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ec96d440-b3f7-4534-add7-7aa202dc21b1' User entered '24 Aug 2020 16:21'	System	24 Aug 2020 21:21:07
	System	24 Aug 2020 21:21:07



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 16:05'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 18:35'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:15:40', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bdf904fc-4561-4ed5-82a5-32e49af21b56'	System	25 Aug 2020 01:16:37
User entered 'None (0)'	System	25 Aug 2020 01:16:37



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:15:51', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bdf904fc-4561-4ed5-82a5-32e49af21b56'	System	25 Aug 2020 01:16:37
User entered 'None (0)'	System	25 Aug 2020 01:16:37



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:16:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bdf904fc-4561-4ed5-82a5-32e49af21b56' User entered 'None (0)'	System	25 Aug 2020 01:16:37
	System	25 Aug 2020 01:16:37



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:16:05', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bdf904fc-4561-4ed5-82a5-32e49af21b56' User entered 'None (0)'	System	25 Aug 2020 01:16:37
	System	25 Aug 2020 01:16:37



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:16:09', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bdf904fc-4561-4ed5-82a5-32e49af21b56'	System	25 Aug 2020 01:16:37
User entered 'None (0)'	System	25 Aug 2020 01:16:37



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:16:13', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bdf904fc-4561-4ed5-82a5-32e49af21b56'	System	25 Aug 2020 01:16:37
User entered 'None (0)'	System	25 Aug 2020 01:16:37



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:16:23', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bdf904fc-4561-4ed5-82a5-32e49af21b56'	System	25 Aug 2020 01:16:37
User entered 'No (N)'	System	25 Aug 2020 01:16:37



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-24T20:16:35', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bdf904fc-4561-4ed5-82a5-32e49af21b56'	System	25 Aug 2020 01:16:37
User entered '24 Aug 2020 20:16'	System	25 Aug 2020 01:16:37



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '24 Aug 2020 19:30'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 2'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:58:51', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bf07f266-8a2a-4cf5-8d40-b2d3d17c84fd' User entered 'None (0)'	System	26 Aug 2020 00:59:34
	System	26 Aug 2020 00:59:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:58:58', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bf07f266-8a2a-4cf5-8d40-b2d3d17c84fd' User entered 'None (0)'	System	26 Aug 2020 00:59:34
	System	26 Aug 2020 00:59:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:59:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bf07f266-8a2a-4cf5-8d40-b2d3d17c84fd' User entered 'None (0)'	System	26 Aug 2020 00:59:34
	System	26 Aug 2020 00:59:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:59:07', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bf07f266-8a2a-4cf5-8d40-b2d3d17c84fd'	System	26 Aug 2020 00:59:34
User entered 'None (0)'	System	26 Aug 2020 00:59:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:59:10', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bf07f266-8a2a-4cf5-8d40-b2d3d17c84fd'	System	26 Aug 2020 00:59:34
User entered 'None (0)'	System	26 Aug 2020 00:59:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:59:13', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bf07f266-8a2a-4cf5-8d40-b2d3d17c84fd' User entered 'None (0)'	System	26 Aug 2020 00:59:34
	System	26 Aug 2020 00:59:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:59:19', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bf07f266-8a2a-4cf5-8d40-b2d3d17c84fd'	System	26 Aug 2020 00:59:34
User entered 'No (N)'	System	26 Aug 2020 00:59:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-25T19:59:29', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bf07f266-8a2a-4cf5-8d40-b2d3d17c84fd' User entered '25 Aug 2020 19:59'	System	26 Aug 2020 00:59:34
	System	26 Aug 2020 00:59:34



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 3'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:10:25', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1b40075d-55a0-476f-98ba-e43dd6d9f5eb' User entered 'None (0)'	System	27 Aug 2020 01:11:18
	System	27 Aug 2020 01:11:18



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:10:30', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1b40075d-55a0-476f-98ba-e43dd6d9f5eb' User entered 'None (0)'	System	27 Aug 2020 01:11:18
	System	27 Aug 2020 01:11:18



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:10:33', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1b40075d-55a0-476f-98ba-e43dd6d9f5eb' User entered 'None (0)'	System	27 Aug 2020 01:11:18
	System	27 Aug 2020 01:11:18



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:10:37', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1b40075d-55a0-476f-98ba-e43dd6d9f5eb' User entered 'None (0)'	System	27 Aug 2020 01:11:18
	System	27 Aug 2020 01:11:18



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:10:40', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1b40075d-55a0-476f-98ba-e43dd6d9f5eb' User entered 'None (0)'	System	27 Aug 2020 01:11:18
	System	27 Aug 2020 01:11:18



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:10:44', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1b40075d-55a0-476f-98ba-e43dd6d9f5eb' User entered 'None (0)'	System	27 Aug 2020 01:11:18
	System	27 Aug 2020 01:11:18



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:10:52', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1b40075d-55a0-476f-98ba-e43dd6d9f5eb'	System	27 Aug 2020 01:11:18
User entered 'No (N)'	System	27 Aug 2020 01:11:18



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-26T20:11:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1b40075d-55a0-476f-98ba-e43dd6d9f5eb'	System	27 Aug 2020 01:11:18
User entered '26 Aug 2020 20:11'	System	27 Aug 2020 01:11:18



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 4'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:02:46', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b1deea6e-ea87-408e-884e-b2a416b7b3bc' User entered 'None (0)'	System	28 Aug 2020 01:03:36
	System	28 Aug 2020 01:03:36



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:02:55', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b1deea6e-ea87-408e-884e-b2a416b7b3bc' User entered 'None (0)'	System	28 Aug 2020 01:03:36
	System	28 Aug 2020 01:03:36



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:03:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b1deea6e-ea87-408e-884e-b2a416b7b3bc' User entered 'None (0)'	System	28 Aug 2020 01:03:36
	System	28 Aug 2020 01:03:36



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:03:06', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b1deea6e-ea87-408e-884e-b2a416b7b3bc' User entered 'None (0)'	System	28 Aug 2020 01:03:36
	System	28 Aug 2020 01:03:36



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:03:09', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b1deea6e-ea87-408e-884e-b2a416b7b3bc' User entered 'None (0)'	System	28 Aug 2020 01:03:36
	System	28 Aug 2020 01:03:36



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:03:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b1deea6e-ea87-408e-884e-b2a416b7b3bc' User entered 'None (0)'	System	28 Aug 2020 01:03:36
	System	28 Aug 2020 01:03:36



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:03:17', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b1deea6e-ea87-408e-884e-b2a416b7b3bc'	System	28 Aug 2020 01:03:36
User entered 'No (N)'	System	28 Aug 2020 01:03:36



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-27T20:03:32', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b1deea6e-ea87-408e-884e-b2a416b7b3bc' User entered '27 Aug 2020 20:03'	System	28 Aug 2020 01:03:36
	System	28 Aug 2020 01:03:36



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 5'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:47', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7da2fdc3-f814-4176-a7dc-59ca2c0561fa' User entered 'None (0)'	System	29 Aug 2020 01:01:19
	System	29 Aug 2020 01:01:19



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:50', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7da2fdc3-f814-4176-a7dc-59ca2c0561fa' User entered 'None (0)'	System	29 Aug 2020 01:01:19
	System	29 Aug 2020 01:01:19



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:53', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7da2fdc3-f814-4176-a7dc-59ca2c0561fa' User entered 'None (0)'	System	29 Aug 2020 01:01:19
	System	29 Aug 2020 01:01:19



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:56', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7da2fdc3-f814-4176-a7dc-59ca2c0561fa' User entered 'None (0)'	System	29 Aug 2020 01:01:19
	System	29 Aug 2020 01:01:19



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:00:59', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7da2fdc3-f814-4176-a7dc-59ca2c0561fa' User entered 'None (0)'	System	29 Aug 2020 01:01:19
	System	29 Aug 2020 01:01:19



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:01:01', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7da2fdc3-f814-4176-a7dc-59ca2c0561fa' User entered 'None (0)'	System	29 Aug 2020 01:01:19
	System	29 Aug 2020 01:01:19



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:01:06', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7da2fdc3-f814-4176-a7dc-59ca2c0561fa'	System	29 Aug 2020 01:01:19
User entered 'No (N)'	System	29 Aug 2020 01:01:19



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-28T20:01:17', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7da2fdc3-f814-4176-a7dc-59ca2c0561fa' User entered '28 Aug 2020 20:01'	System	29 Aug 2020 01:01:19
	System	29 Aug 2020 01:01:19



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 6'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:54', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1ca12ebe-c60e-4dd7-b5c3-56586a2f5b08'	System	30 Aug 2020 00:33:35
User entered 'None (0)'	System	30 Aug 2020 00:33:35



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:32:58', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1ca12ebe-c60e-4dd7-b5c3-56586a2f5b08' User entered 'None (0)'	System	30 Aug 2020 00:33:35
	System	30 Aug 2020 00:33:35



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:33:01', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1ca12ebe-c60e-4dd7-b5c3-56586a2f5b08' User entered 'None (0)'	System	30 Aug 2020 00:33:35
	System	30 Aug 2020 00:33:35



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:33:04', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1ca12ebe-c60e-4dd7-b5c3-56586a2f5b08' User entered 'None (0)'	System	30 Aug 2020 00:33:35
	System	30 Aug 2020 00:33:35



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:33:08', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1ca12ebe-c60e-4dd7-b5c3-56586a2f5b08' User entered 'None (0)'	System	30 Aug 2020 00:33:35
	System	30 Aug 2020 00:33:35



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:33:11', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1ca12ebe-c60e-4dd7-b5c3-56586a2f5b08'	System	30 Aug 2020 00:33:35
User entered 'None (0)'	System	30 Aug 2020 00:33:35



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:33:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1ca12ebe-c60e-4dd7-b5c3-56586a2f5b08'	System	30 Aug 2020 00:33:35
User entered 'No (N)'	System	30 Aug 2020 00:33:35



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-29T19:33:32', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1ca12ebe-c60e-4dd7-b5c3-56586a2f5b08' User entered '29 Aug 2020 19:33'	System	30 Aug 2020 00:33:35
	System	30 Aug 2020 00:33:35



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 7'	System	24 Aug 2020 20:49:57



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:36', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8af9dc33-aaf7-49f1-82a0-e5743ba048ca' User entered 'None (0)'	System	31 Aug 2020 00:38:34
	System	31 Aug 2020 00:38:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8af9dc33-aaf7-49f1-82a0-e5743ba048ca' User entered 'None (0)'	System	31 Aug 2020 00:38:34
	System	31 Aug 2020 00:38:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:42', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8af9dc33-aaf7-49f1-82a0-e5743ba048ca' User entered 'None (0)'	System	31 Aug 2020 00:38:34
	System	31 Aug 2020 00:38:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:46', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8af9dc33-aaf7-49f1-82a0-e5743ba048ca' User entered 'None (0)'	System	31 Aug 2020 00:38:34
	System	31 Aug 2020 00:38:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:48', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8af9dc33-aaf7-49f1-82a0-e5743ba048ca' User entered 'None (0)'	System	31 Aug 2020 00:38:34
	System	31 Aug 2020 00:38:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:33:51', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8af9dc33-aaf7-49f1-82a0-e5743ba048ca' User entered 'None (0)'	System	31 Aug 2020 00:38:34
	System	31 Aug 2020 00:38:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:34:02', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8af9dc33-aaf7-49f1-82a0-e5743ba048ca'	System	31 Aug 2020 00:38:34
User entered 'No (N)'	System	31 Aug 2020 00:38:34



US3312249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-08-30T19:34:15', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8af9dc33-aaf7-49f1-82a0-e5743ba048ca' User entered '30 Aug 2020 19:34'	System	31 Aug 2020 00:38:34
	System	31 Aug 2020 00:38:34



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:50



**US3312249**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '31 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:50



**US3312249**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:50



**US3312249**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4)	10 Sep 2020 00:20:50
	Karol Moore (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:20:53



**US3312249**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'I'	System	10 Sep 2020 00:20:53



**US3312249**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:21:11



**US3312249**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '7 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:21:11



**US3312249**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:21:11



**US3312249**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4)	10 Sep 2020 00:21:11
	Karol Moore (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:21:15



**US3312249**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:33:29
User entered 'I'	System	10 Sep 2020 00:21:15



**US3312249**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 00:38:42



**US3312249**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '14 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 00:38:42



**US3312249**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	24 Sep 2020 00:38:42



**US3312249**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4)	24 Sep 2020 00:38:42
	Karol Moore (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	24 Sep 2020 00:38:45



**US3312249**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:11
User entered 'I'	System	24 Sep 2020 00:38:45



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:45



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:45



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:45



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'VISIT2'	System	28 Sep 2020 15:57:45



US3312249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	18 Oct 2020 22:00:49
	(b) (4)	



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '28 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '09:08'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered '28 Sep 2020 09:08'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '98.2' F	(b) (4) Karol Moore (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '59'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'bpm'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'breaths/min'	System	18 Oct 2020 22:00:49



US3312249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '137'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'mmHg'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '88'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'mmHg'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '28 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '11:25'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered '28 Sep 2020 11:25'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '97.9' F	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '55'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'bpm'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'breaths/min'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '132'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'mmHg'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '82'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'mmHg'	System	18 Oct 2020 22:00:49



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:57



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '28 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:00:57



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:58:05



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:58:05



US3312249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:58:05



US3312249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:58:05



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '10:54'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:58:05



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered '28 Sep 2020 10:54'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:58:05



US3312249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'ONCE'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:57:13**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:01:10



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '28 Sep 2020'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 22:01:10



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '10:17'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:01:10



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered '28 Sep 2020 10:17'	System	18 Oct 2020 22:01:10



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 16:57:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '28 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '10:04'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered '28 Sep 2020 10:04'	System	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4)	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered empty.	System	18 Oct 2020 22:01:21



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:58:18



**US3312249**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'I'	System	28 Sep 2020 15:58:18



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:26:26', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2b8f036a-ecd1-4077-8eef-d366f03ea469' User entered 'Yes (Y)'	System	28 Sep 2020 16:26:59
	System	28 Sep 2020 16:26:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:26:35', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2b8f036a-ecd1-4077-8eef-d366f03ea469'	System	28 Sep 2020 16:26:59
User entered '97.9'	System	28 Sep 2020 16:26:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:26:42', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2b8f036a-ecd1-4077-8eef-d366f03ea469'	System	28 Sep 2020 16:26:59
User entered 'No (N)'	System	28 Sep 2020 16:26:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:26:55', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2b8f036a-ecd1-4077-8eef-d366f03ea469'	System	28 Sep 2020 16:26:59
User entered '28 Sep 2020 11:26'	System	28 Sep 2020 16:26:59



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 11:14'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 13:44'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T19:59:13', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '51f4d819-7d2d-4406-91c7-f10dfb803933'	System	29 Sep 2020 00:59:53
User entered 'Yes (Y)'	System	29 Sep 2020 00:59:53



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T19:59:32', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '51f4d819-7d2d-4406-91c7-f10dfb803933' User entered '97.9'	System	29 Sep 2020 00:59:53
	System	29 Sep 2020 00:59:53



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T19:59:37', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '51f4d819-7d2d-4406-91c7-f10dfb803933'	System	29 Sep 2020 00:59:53
User entered 'No (N)'	System	29 Sep 2020 00:59:53



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T19:59:48', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '51f4d819-7d2d-4406-91c7-f10dfb803933'	System	29 Sep 2020 00:59:53
User entered '28 Sep 2020 19:59'	System	29 Sep 2020 00:59:53



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 2'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:38:40', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '9f756ead-8ab8-4286-8559-1396f249faac'	System	30 Sep 2020 00:39:58
User entered 'Yes (Y)'	System	30 Sep 2020 00:39:58



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:38:49', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '9f756ead-8ab8-4286-8559-1396f249faac'	System	30 Sep 2020 00:39:58
User entered '96.9'	System	30 Sep 2020 00:39:58



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:38:56', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '9f756ead-8ab8-4286-8559-1396f249faac'	System	30 Sep 2020 00:39:58
User entered 'Yes (Y)'	System	30 Sep 2020 00:39:58



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 06:06:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karol Moore (b) (4)	18 Oct 2020 22:01:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:39:07', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '9f756ead-8ab8-4286-8559-1396f249faac'	System	30 Sep 2020 00:39:58
User entered '1'	System	30 Sep 2020 00:39:58



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:39:07', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '9f756ead-8ab8-4286-8559-1396f249faac'	System	30 Sep 2020 00:39:58
User entered '0'	System	30 Sep 2020 00:39:58



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:39:47', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '9f756ead-8ab8-4286-8559-1396f249faac'	System	30 Sep 2020 00:39:58
User entered '29 Sep 2020 19:39'	System	30 Sep 2020 00:39:58



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 3'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:03:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '11c02ac0-2601-4f6c-84c0-f4eb18fe4864' User entered 'Yes (Y)'	System	01 Oct 2020 01:03:51
	System	01 Oct 2020 01:03:51



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:03:35', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '11c02ac0-2601-4f6c-84c0-f4eb18fe4864' User entered '97.5'	System	01 Oct 2020 01:03:51
	System	01 Oct 2020 01:03:51



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:03:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '11c02ac0-2601-4f6c-84c0-f4eb18fe4864'	System	01 Oct 2020 01:03:51
User entered 'No (N)'	System	01 Oct 2020 01:03:51



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:03:47', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '11c02ac0-2601-4f6c-84c0-f4eb18fe4864' User entered '30 Sep 2020 20:03'	System	01 Oct 2020 01:03:51
	System	01 Oct 2020 01:03:51



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 4'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:28:05', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '730ae6bb-efb1-42c7-833d-77ba9a13ad82' User entered 'Yes (Y)'	System	02 Oct 2020 00:28:27
	System	02 Oct 2020 00:28:27



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:28:11', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '730ae6bb-efb1-42c7-833d-77ba9a13ad82'	System	02 Oct 2020 00:28:27
User entered '96.8'	System	02 Oct 2020 00:28:27



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:28:16', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '730ae6bb-efb1-42c7-833d-77ba9a13ad82'	System	02 Oct 2020 00:28:27
User entered 'No (N)'	System	02 Oct 2020 00:28:27



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:28:23', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '730ae6bb-efb1-42c7-833d-77ba9a13ad82'	System	02 Oct 2020 00:28:27
User entered '01 Oct 2020 19:28'	System	02 Oct 2020 00:28:27



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 5'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:09', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '26add64d-a007-45dc-850d-f947dfca82da' User entered 'Yes (Y)'	System	03 Oct 2020 00:41:30
	System	03 Oct 2020 00:41:30



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:17', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '26add64d-a007-45dc-850d-f947dfca82da' User entered '98.7'	System	03 Oct 2020 00:41:30
	System	03 Oct 2020 00:41:30



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '26add64d-a007-45dc-850d-f947dfca82da' User entered 'No (N)'	System	03 Oct 2020 00:41:30
	System	03 Oct 2020 00:41:30



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '26add64d-a007-45dc-850d-f947dfca82da' User entered '02 Oct 2020 19:41'	System	03 Oct 2020 00:41:30
	System	03 Oct 2020 00:41:30



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 6'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:26:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ac7c7c97-a38a-4984-ac4b-676a8e90e22e' User entered 'Yes (Y)'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:26:33', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ac7c7c97-a38a-4984-ac4b-676a8e90e22e' User entered '98.6'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:26:38', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ac7c7c97-a38a-4984-ac4b-676a8e90e22e' User entered 'Yes (Y)'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT CONFIRMED. MEDICATION DETAILS ADDED TO CONCOMITANT MEDICATION PAGES' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 06:06:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karol Moore (b) (4)	18 Oct 2020 22:01:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:26:45', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ac7c7c97-a38a-4984-ac4b-676a8e90e22e'	(b) (4)	
User entered '1'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:26:45', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ac7c7c97-a38a-4984-ac4b-676a8e90e22e' User entered '0'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:26:59', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ac7c7c97-a38a-4984-ac4b-676a8e90e22e' User entered '03 Oct 2020 19:26'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 7'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:03:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '463109b6-a120-4e58-9165-edc2bc42202e' User entered 'Yes (Y)'	System	05 Oct 2020 01:03:31
	System	05 Oct 2020 01:03:31



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:03:18', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '463109b6-a120-4e58-9165-edc2bc42202e' User entered '98.8'	System	05 Oct 2020 01:03:31
	System	05 Oct 2020 01:03:31



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:03:23', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '463109b6-a120-4e58-9165-edc2bc42202e' User entered 'No (N)'	System	05 Oct 2020 01:03:31
	System	05 Oct 2020 01:03:31



US3312249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:03:28', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '463109b6-a120-4e58-9165-edc2bc42202e' User entered '04 Oct 2020 20:03'	System	05 Oct 2020 01:03:31
	System	05 Oct 2020 01:03:31



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:27:17', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b86ac8b6-f31d-47b6-b7da-7e03c46fd9d6'	System	28 Sep 2020 16:27:48
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 16:27:48



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:27:25', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b86ac8b6-f31d-47b6-b7da-7e03c46fd9d6'	System	28 Sep 2020 16:27:48
User entered 'No (N)'	System	28 Sep 2020 16:27:48



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:27:29', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b86ac8b6-f31d-47b6-b7da-7e03c46fd9d6' User entered 'No (N)'	System	28 Sep 2020 16:27:48
	System	28 Sep 2020 16:27:48



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:27:38', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b86ac8b6-f31d-47b6-b7da-7e03c46fd9d6' User entered 'None (1)'	System	28 Sep 2020 16:27:48
	System	28 Sep 2020 16:27:48



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:27:46', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b86ac8b6-f31d-47b6-b7da-7e03c46fd9d6'	System	28 Sep 2020 16:27:48
User entered '28 Sep 2020 11:27'	System	28 Sep 2020 16:27:48



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 11:14'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 13:44'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T19:59:56', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '69ef50e3-9504-4e72-adb1-31d7734a4c4b' User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 01:00:30
	System	29 Sep 2020 01:00:30



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:02', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '69ef50e3-9504-4e72-adb1-31d7734a4c4b' User entered 'No (N)'	System	29 Sep 2020 01:00:30
	System	29 Sep 2020 01:00:30



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:14', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '69ef50e3-9504-4e72-adb1-31d7734a4c4b' User entered 'No (N)'	System	29 Sep 2020 01:00:30
	System	29 Sep 2020 01:00:30



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:19', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '69ef50e3-9504-4e72-adb1-31d7734a4c4b' User entered 'None (1)'	System	29 Sep 2020 01:00:30
	System	29 Sep 2020 01:00:30



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '69ef50e3-9504-4e72-adb1-31d7734a4c4b' User entered '28 Sep 2020 20:00'	System	29 Sep 2020 01:00:30
	System	29 Sep 2020 01:00:30



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 2'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:39:58', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4b8f2a80-c6ce-423f-9a94-df62adfc1536'	System	30 Sep 2020 00:40:47
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 00:40:47



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:40:02', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4b8f2a80-c6ce-423f-9a94-df62adfc1536'	System	30 Sep 2020 00:40:47
User entered 'Yes (Y)'	System	30 Sep 2020 00:40:47



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:40:13', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4b8f2a80-c6ce-423f-9a94-df62adfc1536'	System	30 Sep 2020 00:40:47
User entered '80'	System	30 Sep 2020 00:40:47



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:40:19', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4b8f2a80-c6ce-423f-9a94-df62adfc1536'	System	30 Sep 2020 00:40:47
User entered 'No (N)'	System	30 Sep 2020 00:40:47



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:40:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4b8f2a80-c6ce-423f-9a94-df62adfc1536'	System	30 Sep 2020 00:40:47
User entered 'None (1)'	System	30 Sep 2020 00:40:47



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:40:41', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '4b8f2a80-c6ce-423f-9a94-df62adfc1536'	System	30 Sep 2020 00:40:47
User entered '29 Sep 2020 19:40'	System	30 Sep 2020 00:40:47



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 3'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:03:57', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1423ce0e-e7b4-43b4-85c0-056fe2a5f540'	System	01 Oct 2020 01:05:31
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 01:05:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:04:01', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1423ce0e-e7b4-43b4-85c0-056fe2a5f540' User entered 'Yes (Y)'	System	01 Oct 2020 01:05:31
	System	01 Oct 2020 01:05:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:04:11', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1423ce0e-e7b4-43b4-85c0-056fe2a5f540' User entered '120'	System	01 Oct 2020 01:05:31
	System	01 Oct 2020 01:05:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:04:19', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1423ce0e-e7b4-43b4-85c0-056fe2a5f540' User entered 'No (N)'	System	01 Oct 2020 01:05:31
	System	01 Oct 2020 01:05:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:04:55', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1423ce0e-e7b4-43b4-85c0-056fe2a5f540' User entered 'None (1)'	System	01 Oct 2020 01:05:31
	System	01 Oct 2020 01:05:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:05:30', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '1423ce0e-e7b4-43b4-85c0-056fe2a5f540' User entered '30 Sep 2020 20:05'	System	01 Oct 2020 01:05:31
	System	01 Oct 2020 01:05:31



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 4'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:28:37', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c95e4aec-4a74-482e-9288-91139f539b96'	System	02 Oct 2020 00:29:19
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 00:29:19



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:28:42', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c95e4aec-4a74-482e-9288-91139f539b96'	System	02 Oct 2020 00:29:19
User entered 'Yes (Y)'	System	02 Oct 2020 00:29:19



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:28:54', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c95e4aec-4a74-482e-9288-91139f539b96'	System	02 Oct 2020 00:29:19
User entered '150'	System	02 Oct 2020 00:29:19



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:28:59', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c95e4aec-4a74-482e-9288-91139f539b96'	System	02 Oct 2020 00:29:19
User entered 'No (N)'	System	02 Oct 2020 00:29:19



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:29:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c95e4aec-4a74-482e-9288-91139f539b96'	System	02 Oct 2020 00:29:19
User entered 'None (1)'	System	02 Oct 2020 00:29:19



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:29:16', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c95e4aec-4a74-482e-9288-91139f539b96'	System	02 Oct 2020 00:29:19
User entered '01 Oct 2020 19:29'	System	02 Oct 2020 00:29:19



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 5'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:36', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a9a0627b-779c-4717-ad33-b25043cab797' User entered 'None (1)'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:40', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a9a0627b-779c-4717-ad33-b25043cab797' User entered 'Yes (Y)'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:47', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a9a0627b-779c-4717-ad33-b25043cab797'	System	03 Oct 2020 00:42:31
User entered '150'	System	03 Oct 2020 00:42:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:52', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a9a0627b-779c-4717-ad33-b25043cab797' User entered 'No (N)'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:41:58', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a9a0627b-779c-4717-ad33-b25043cab797' User entered 'None (1)'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:42:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a9a0627b-779c-4717-ad33-b25043cab797' User entered '02 Oct 2020 19:42'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 6'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:27:06', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '68623013-4100-4890-832f-fd22042b5f63'	System	04 Oct 2020 00:40:42
User entered 'None (1)'	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:27:09', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '68623013-4100-4890-832f-fd22042b5f63'	System	04 Oct 2020 00:40:42
User entered 'Yes (Y)'	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:27:15', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '68623013-4100-4890-832f-fd22042b5f63' User entered '75'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:27:19', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '68623013-4100-4890-832f-fd22042b5f63' User entered 'No (N)'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:27:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '68623013-4100-4890-832f-fd22042b5f63' User entered 'None (1)'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:28:05', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '68623013-4100-4890-832f-fd22042b5f63' User entered '03 Oct 2020 19:28'	System	04 Oct 2020 00:40:42
	System	04 Oct 2020 00:40:42



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 7'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:03:35', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c52203c5-ee71-49ea-9826-233486ba2048' User entered 'None (1)'	System	05 Oct 2020 01:04:13
	System	05 Oct 2020 01:04:13



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:03:42', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c52203c5-ee71-49ea-9826-233486ba2048' User entered 'No (N)'	System	05 Oct 2020 01:04:13
	System	05 Oct 2020 01:04:13



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:03:45', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c52203c5-ee71-49ea-9826-233486ba2048' User entered 'No (N)'	System	05 Oct 2020 01:04:13
	System	05 Oct 2020 01:04:13



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:03:58', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c52203c5-ee71-49ea-9826-233486ba2048' User entered 'None (1)'	System	05 Oct 2020 01:04:13
	System	05 Oct 2020 01:04:13



US3312249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:04:10', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c52203c5-ee71-49ea-9826-233486ba2048' User entered '04 Oct 2020 20:04'	System	05 Oct 2020 01:04:13
	System	05 Oct 2020 01:04:13



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:27:54', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7c8e55d3-a924-4eee-a3b2-46e016273a29' User entered 'None (0)'	System	28 Sep 2020 16:28:24
	System	28 Sep 2020 16:28:24



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:27:57', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7c8e55d3-a924-4eee-a3b2-46e016273a29' User entered 'None (0)'	System	28 Sep 2020 16:28:24
	System	28 Sep 2020 16:28:24



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:28:02', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7c8e55d3-a924-4eee-a3b2-46e016273a29' User entered 'None (0)'	System	28 Sep 2020 16:28:24
	System	28 Sep 2020 16:28:24



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:28:06', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7c8e55d3-a924-4eee-a3b2-46e016273a29' User entered 'None (0)'	System	28 Sep 2020 16:28:24
	System	28 Sep 2020 16:28:24



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:28:10', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7c8e55d3-a924-4eee-a3b2-46e016273a29' User entered 'None (0)'	System	28 Sep 2020 16:28:24
	System	28 Sep 2020 16:28:24



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:28:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7c8e55d3-a924-4eee-a3b2-46e016273a29' User entered 'None (0)'	System	28 Sep 2020 16:28:24
	System	28 Sep 2020 16:28:24



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:28:18', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7c8e55d3-a924-4eee-a3b2-46e016273a29'	System	28 Sep 2020 16:28:24
User entered 'No (N)'	System	28 Sep 2020 16:28:24



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T11:28:22', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '7c8e55d3-a924-4eee-a3b2-46e016273a29' User entered '28 Sep 2020 11:28'	System	28 Sep 2020 16:28:24
	System	28 Sep 2020 16:28:24



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 11:14'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 13:44'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:34', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '05052b12-2cc2-46f0-a7e4-d3782c704fbe' User entered 'None (0)'	System	29 Sep 2020 01:01:09
	System	29 Sep 2020 01:01:09



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:37', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '05052b12-2cc2-46f0-a7e4-d3782c704fbe' User entered 'None (0)'	System	29 Sep 2020 01:01:09
	System	29 Sep 2020 01:01:09



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '05052b12-2cc2-46f0-a7e4-d3782c704fbe' User entered 'None (0)'	System	29 Sep 2020 01:01:09
	System	29 Sep 2020 01:01:09



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:42', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '05052b12-2cc2-46f0-a7e4-d3782c704fbe' User entered 'None (0)'	System	29 Sep 2020 01:01:09
	System	29 Sep 2020 01:01:09



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:44', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '05052b12-2cc2-46f0-a7e4-d3782c704fbe' User entered 'None (0)'	System	29 Sep 2020 01:01:09
	System	29 Sep 2020 01:01:09



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:47', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '05052b12-2cc2-46f0-a7e4-d3782c704fbe' User entered 'None (0)'	System	29 Sep 2020 01:01:09
	System	29 Sep 2020 01:01:09



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:00:53', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '05052b12-2cc2-46f0-a7e4-d3782c704fbe' User entered 'No (N)'	System	29 Sep 2020 01:01:09
	System	29 Sep 2020 01:01:09



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-28T20:01:01', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '05052b12-2cc2-46f0-a7e4-d3782c704fbe' User entered '28 Sep 2020 20:01'	System	29 Sep 2020 01:01:09
	System	29 Sep 2020 01:01:09



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '28 Sep 2020 14:39'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 2'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:40:50', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a003f635-f63f-4062-b17c-bc7aaff73f00' User entered 'None (0)'	System	30 Sep 2020 00:41:44
	System	30 Sep 2020 00:41:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:41:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a003f635-f63f-4062-b17c-bc7aaff73f00' User entered 'None (0)'	System	30 Sep 2020 00:41:44
	System	30 Sep 2020 00:41:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:41:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a003f635-f63f-4062-b17c-bc7aaff73f00'	System	30 Sep 2020 00:41:44
User entered 'Some interference with activity (2)'	System	30 Sep 2020 00:41:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:41:16', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a003f635-f63f-4062-b17c-bc7aaff73f00'	System	30 Sep 2020 00:41:44
User entered 'Some interference with activity (2)'	System	30 Sep 2020 00:41:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:41:20', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a003f635-f63f-4062-b17c-bc7aaff73f00' User entered 'None (0)'	System	30 Sep 2020 00:41:44
	System	30 Sep 2020 00:41:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:41:23', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a003f635-f63f-4062-b17c-bc7aaff73f00'	System	30 Sep 2020 00:41:44
User entered 'None (0)'	System	30 Sep 2020 00:41:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:41:28', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a003f635-f63f-4062-b17c-bc7aaff73f00'	System	30 Sep 2020 00:41:44
User entered 'No (N)'	System	30 Sep 2020 00:41:44



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-29T19:41:41', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a003f635-f63f-4062-b17c-bc7aaff73f00'	System	30 Sep 2020 00:41:44
User entered '29 Sep 2020 19:41'	System	30 Sep 2020 00:41:44



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 3'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:05:37', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '955d4fe7-3edb-4512-acdf-d0cfa2931a17' User entered 'None (0)'	System	01 Oct 2020 01:07:36
	System	01 Oct 2020 01:07:36



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:05:43', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '955d4fe7-3edb-4512-acdf-d0cfa2931a17' User entered 'None (0)'	System	01 Oct 2020 01:07:36
	System	01 Oct 2020 01:07:36



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:05:52', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '955d4fe7-3edb-4512-acdf-d0cfa2931a17'	System	01 Oct 2020 01:07:36
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:07:36



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:05:56', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '955d4fe7-3edb-4512-acdf-d0cfa2931a17'	System	01 Oct 2020 01:07:36
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:07:36



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:06:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '955d4fe7-3edb-4512-acdf-d0cfa2931a17' User entered 'None (0)'	System	01 Oct 2020 01:07:36
	System	01 Oct 2020 01:07:36



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:06:43', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '955d4fe7-3edb-4512-acdf-d0cfa2931a17' User entered 'None (0)'	System	01 Oct 2020 01:07:36
	System	01 Oct 2020 01:07:36



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:06:49', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '955d4fe7-3edb-4512-acdf-d0cfa2931a17'	System	01 Oct 2020 01:07:36
User entered 'No (N)'	System	01 Oct 2020 01:07:36



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-09-30T20:07:32', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '955d4fe7-3edb-4512-acdf-d0cfa2931a17' User entered '30 Sep 2020 20:07'	System	01 Oct 2020 01:07:36
	System	01 Oct 2020 01:07:36



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 4'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:29:27', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ea161782-3e86-48be-ba9b-d9cf509a64fb' User entered 'None (0)'	System	02 Oct 2020 00:30:26
	System	02 Oct 2020 00:30:26



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:29:30', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ea161782-3e86-48be-ba9b-d9cf509a64fb' User entered 'None (0)'	System	02 Oct 2020 00:30:26
	System	02 Oct 2020 00:30:26



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:29:34', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ea161782-3e86-48be-ba9b-d9cf509a64fb' User entered 'None (0)'	System	02 Oct 2020 00:30:26
	System	02 Oct 2020 00:30:26



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:29:37', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ea161782-3e86-48be-ba9b-d9cf509a64fb' User entered 'None (0)'	System	02 Oct 2020 00:30:26
	System	02 Oct 2020 00:30:26



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:29:40', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ea161782-3e86-48be-ba9b-d9cf509a64fb' User entered 'None (0)'	System	02 Oct 2020 00:30:26
	System	02 Oct 2020 00:30:26



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:29:46', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ea161782-3e86-48be-ba9b-d9cf509a64fb' User entered 'None (0)'	System	02 Oct 2020 00:30:26
	System	02 Oct 2020 00:30:26



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:30:09', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ea161782-3e86-48be-ba9b-d9cf509a64fb' User entered 'No (N)'	System	02 Oct 2020 00:30:26
	System	02 Oct 2020 00:30:26



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-01T19:30:24', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'ea161782-3e86-48be-ba9b-d9cf509a64fb' User entered '01 Oct 2020 19:30'	System	02 Oct 2020 00:30:26
	System	02 Oct 2020 00:30:26



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 5'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:42:33', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '49f0dd11-e282-4d89-933c-d93c3ba8a39b' User entered 'None (0)'	System	03 Oct 2020 00:43:25
	System	03 Oct 2020 00:43:25



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:42:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '49f0dd11-e282-4d89-933c-d93c3ba8a39b' User entered 'None (0)'	System	03 Oct 2020 00:43:25
	System	03 Oct 2020 00:43:25



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:42:43', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '49f0dd11-e282-4d89-933c-d93c3ba8a39b' User entered 'None (0)'	System	03 Oct 2020 00:43:25
	System	03 Oct 2020 00:43:25



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:42:45', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '49f0dd11-e282-4d89-933c-d93c3ba8a39b' User entered 'None (0)'	System	03 Oct 2020 00:43:25
	System	03 Oct 2020 00:43:25



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:42:48', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '49f0dd11-e282-4d89-933c-d93c3ba8a39b' User entered 'None (0)'	System	03 Oct 2020 00:43:25
	System	03 Oct 2020 00:43:25



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:42:57', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '49f0dd11-e282-4d89-933c-d93c3ba8a39b' User entered 'None (0)'	System	03 Oct 2020 00:43:25
	System	03 Oct 2020 00:43:25



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:43:04', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '49f0dd11-e282-4d89-933c-d93c3ba8a39b' User entered 'No (N)'	System	03 Oct 2020 00:43:25
	System	03 Oct 2020 00:43:25



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-02T19:43:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '49f0dd11-e282-4d89-933c-d93c3ba8a39b' User entered '02 Oct 2020 19:43'	System	03 Oct 2020 00:43:25
	System	03 Oct 2020 00:43:25



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 6'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:28:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '6d28d5f1-2cb5-4976-a40e-2977229e0d64' User entered 'None (0)'	System	04 Oct 2020 00:40:44
	System	04 Oct 2020 00:40:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:28:18', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '6d28d5f1-2cb5-4976-a40e-2977229e0d64'	System	04 Oct 2020 00:40:44
User entered 'No interference with activity (1)'	System	04 Oct 2020 00:40:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:28:31', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '6d28d5f1-2cb5-4976-a40e-2977229e0d64'	System	04 Oct 2020 00:40:44
User entered 'Some interference with activity (2)'	System	04 Oct 2020 00:40:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:28:35', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '6d28d5f1-2cb5-4976-a40e-2977229e0d64'	System	04 Oct 2020 00:40:44
User entered 'Some interference with activity (2)'	System	04 Oct 2020 00:40:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:28:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '6d28d5f1-2cb5-4976-a40e-2977229e0d64' User entered 'None (0)'	System	04 Oct 2020 00:40:44
	System	04 Oct 2020 00:40:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:28:42', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '6d28d5f1-2cb5-4976-a40e-2977229e0d64' User entered 'None (0)'	System	04 Oct 2020 00:40:44
	System	04 Oct 2020 00:40:44



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:28:50', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '6d28d5f1-2cb5-4976-a40e-2977229e0d64'	System	04 Oct 2020 00:40:44
User entered 'No (N)'	System	04 Oct 2020 00:40:44



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-03T19:29:13', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '6d28d5f1-2cb5-4976-a40e-2977229e0d64' User entered '03 Oct 2020 19:29'	System	04 Oct 2020 00:40:44
	System	04 Oct 2020 00:40:44



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	28 Sep 2020 15:58:05
User entered 'Day 7'	System	28 Sep 2020 15:58:05



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:04:17', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bef0195-7576-4fce-99a7-4db1276c1865' User entered 'None (0)'	System	05 Oct 2020 01:05:22
	System	05 Oct 2020 01:05:22



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:04:28', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bef0195-7576-4fce-99a7-4db1276c1865'	System	05 Oct 2020 01:05:22
User entered 'No interference with activity (1)'	System	05 Oct 2020 01:05:22



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:04:32', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bef0195-7576-4fce-99a7-4db1276c1865' User entered 'None (0)'	System	05 Oct 2020 01:05:22
	System	05 Oct 2020 01:05:22



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:05:06', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bef0195-7576-4fce-99a7-4db1276c1865'	System	05 Oct 2020 01:05:22
User entered 'No interference with activity (1)'	System	05 Oct 2020 01:05:22



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:04:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bef0195-7576-4fce-99a7-4db1276c1865' User entered 'None (0)'	System	05 Oct 2020 01:05:22
	System	05 Oct 2020 01:05:22



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:04:45', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bef0195-7576-4fce-99a7-4db1276c1865' User entered 'None (0)'	System	05 Oct 2020 01:05:22
	System	05 Oct 2020 01:05:22



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:04:49', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bef0195-7576-4fce-99a7-4db1276c1865'	System	05 Oct 2020 01:05:22
User entered 'No (N)'	System	05 Oct 2020 01:05:22



US3312249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-04T20:05:20', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bef0195-7576-4fce-99a7-4db1276c1865' User entered '04 Oct 2020 20:05'	System	05 Oct 2020 01:05:22
	System	05 Oct 2020 01:05:22



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:58:05



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	04 Oct 2020 00:40:44
User entered 'Day 8'	System	04 Oct 2020 00:40:44



US3312249

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:57:13

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-05T19:20:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bcf64dd9-2f1b-4264-bd9f-5e704b39e8c7' User entered 'None (0)'	System	06 Oct 2020 00:20:45
	System	06 Oct 2020 00:20:45



US3312249

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-05T19:20:44', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'bcf64dd9-2f1b-4264-bd9f-5e704b39e8c7'	System	06 Oct 2020 00:20:45
User entered '05 Oct 2020 19:20'	System	06 Oct 2020 00:20:45



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 00:40:44



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 00:40:44



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	04 Oct 2020 00:40:44
User entered 'Day 8'	System	04 Oct 2020 00:40:44



US3312249

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:57:13

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-05T19:20:50', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '161aef71-67fa-4119-9879-36d112fa3ac2'	System	06 Oct 2020 00:21:01
User entered 'None (0)'	System	06 Oct 2020 00:21:01



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-05T19:20:58', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '161aef71-67fa-4119-9879-36d112fa3ac2'	System	06 Oct 2020 00:21:01
User entered '05 Oct 2020 19:20'	System	06 Oct 2020 00:21:01



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 00:40:44



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 00:40:44



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	04 Oct 2020 00:40:42
User entered 'Day 8'	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-05T19:21:04', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd3839b1e-e126-48c1-8b4f-2080462862ca' User entered 'No (N)'	System	06 Oct 2020 00:21:12
	System	06 Oct 2020 00:21:12



US3312249

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-05T19:21:08', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd3839b1e-e126-48c1-8b4f-2080462862ca' User entered '05 Oct 2020 19:21'	System	06 Oct 2020 00:21:12
	System	06 Oct 2020 00:21:12



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 00:40:42



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 00:40:42



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
Data entry locked.	System	04 Oct 2020 00:40:42
User entered 'Day 8'	System	04 Oct 2020 00:40:42



US3312249

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:57:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 23:55:55



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 23:55:55



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 00:40:42



**US3312249**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:55:55
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 00:40:42



**US3312249**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:03:16



US3312249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	18 Oct 2020 22:03:34
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	18 Oct 2020 22:03:34
User entered '05 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	18 Oct 2020 22:03:34
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	18 Oct 2020 22:03:16
User entered '28 Sep 2020'	System	18 Oct 2020 22:03:16
	Karol Moore (b) (4)	18 Oct 2020 22:03:16
	(b) (4)	



**US3312249**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:03:16



**US3312249**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4)	18 Oct 2020 22:03:16
	(b) (4)	



**US3312249**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 22:04:05



**US3312249**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'I'	System	18 Oct 2020 22:04:05



**US3312249**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:04:16



**US3312249**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '12 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:04:16



**US3312249**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 22:04:16



**US3312249**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:04:16



**US3312249**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	18 Oct 2020 22:04:34



**US3312249**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'I'	System	18 Oct 2020 22:04:34



**US3312249**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:32:22



**US3312249**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:32:22



**US3312249**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:32:22



**US3312249**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:32:22



**US3312249**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:32:25



**US3312249**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'I'	System	20 Oct 2020 16:32:25



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:00



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:00



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:00



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'VISIT3'	System	28 Oct 2020 15:22:00



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '08:20'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered '23 Oct 2020 08:20'	System	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '67'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'bpm'	System	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '12'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'breaths/min'	System	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '140'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'mmHg'	System	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '70'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'mmHg'	System	28 Oct 2020 15:22:20



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:27



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:27



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:37



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:37



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered '08:40'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:37



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered '23 Oct 2020 08:40'	System	28 Oct 2020 15:22:37



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:23:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:22:43



**US3312249**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'I'	System	28 Oct 2020 15:22:43



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 64'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-25T13:10:05', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '988129a8-b041-4320-912b-0b0c713f38ef' User entered 'No (N)'	System	25 Oct 2020 18:10:25
	System	25 Oct 2020 18:10:25



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-25T13:10:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '988129a8-b041-4320-912b-0b0c713f38ef' User entered 'No (N)'	System	25 Oct 2020 18:10:25
	System	25 Oct 2020 18:10:25



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-10-25T13:10:22', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '988129a8-b041-4320-912b-0b0c713f38ef' User entered '25 Oct 2020 13:10:22'	System	25 Oct 2020 18:10:25
	System	25 Oct 2020 18:10:25



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 71'	System	24 Aug 2020 20:49:57



US3312249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-02T19:44:33', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '58bd7ab4-1ede-42e7-a80d-a201d0112594' User entered 'No (N)'	System	03 Nov 2020 00:44:44
	System	03 Nov 2020 00:44:44



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-02T19:44:36', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '58bd7ab4-1ede-42e7-a80d-a201d0112594'	System	03 Nov 2020 00:44:44
User entered 'No (N)'	System	03 Nov 2020 00:44:44



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-02T19:44:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '58bd7ab4-1ede-42e7-a80d-a201d0112594' User entered '02 Nov 2020 19:44:39'	System	03 Nov 2020 00:44:44
	System	03 Nov 2020 00:44:44



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered 'Day 78'	System	24 Aug 2020 20:49:57



US3312249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-08T11:58:02', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '91590624-5915-47b1-b65d-2d86991846cd' User entered 'No (N)'	System	08 Nov 2020 17:58:26
	System	08 Nov 2020 17:58:26



US3312249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-08T11:58:08', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '91590624-5915-47b1-b65d-2d86991846cd' User entered 'No (N)'	System	08 Nov 2020 17:58:26
	System	08 Nov 2020 17:58:26



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-08T11:58:21', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '91590624-5915-47b1-b65d-2d86991846cd' User entered '08 Nov 2020 11:58:21'	System	08 Nov 2020 17:58:26
	System	08 Nov 2020 17:58:26



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:26
Data entry locked.	System	24 Aug 2020 20:49:57
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 20:49:57



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-21T06:59:59', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3039cb59-0f1d-4cee-b70d-a421ea559b07'	System	21 Nov 2020 13:00:59
User entered 'No (N)'	System	21 Nov 2020 13:00:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-21T07:00:15', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3039cb59-0f1d-4cee-b70d-a421ea559b07'	System	21 Nov 2020 13:00:59
User entered 'Yes (Y)'	System	21 Nov 2020 13:00:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-21T07:00:36', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3039cb59-0f1d-4cee-b70d-a421ea559b07'	System	21 Nov 2020 13:00:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 13:00:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-21T07:00:49', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3039cb59-0f1d-4cee-b70d-a421ea559b07'	System	21 Nov 2020 13:00:59
User entered '21 Nov 2020 07:00:49'	System	21 Nov 2020 13:00:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-26T07:13:15', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'dfbca753-324e-4ef7-ba39-e9e131d36916'	System	26 Nov 2020 13:13:39
User entered 'No (N)'	System	26 Nov 2020 13:13:39



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-26T07:13:29', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'dfbca753-324e-4ef7-ba39-e9e131d36916'	System	26 Nov 2020 13:13:39
User entered 'No (N)'	System	26 Nov 2020 13:13:39



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-11-26T07:13:36', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'dfbca753-324e-4ef7-ba39-e9e131d36916' User entered '26 Nov 2020 07:13:36'	System	26 Nov 2020 13:13:39
	System	26 Nov 2020 13:13:39



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-02T07:44:07', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '70d9f02b-eadf-4bc9-9408-e26bc9456288' User entered 'No (N)'	System	02 Dec 2020 13:44:23
	System	02 Dec 2020 13:44:23



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-02T07:44:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '70d9f02b-eadf-4bc9-9408-e26bc9456288'	System	02 Dec 2020 13:44:23
User entered 'No (N)'	System	02 Dec 2020 13:44:23



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-02T07:44:15', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '70d9f02b-eadf-4bc9-9408-e26bc9456288' User entered '02 Dec 2020 07:44:15'	System	02 Dec 2020 13:44:23
	System	02 Dec 2020 13:44:23



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-09T12:48:31', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3b608bd8-92a9-4ef3-b9af-f6214ce84598'	System	09 Dec 2020 17:48:45
User entered 'No (N)'	System	09 Dec 2020 17:48:45



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-09T12:48:37', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3b608bd8-92a9-4ef3-b9af-f6214ce84598'	System	09 Dec 2020 17:48:45
User entered 'No (N)'	System	09 Dec 2020 17:48:45



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-09T12:48:42', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3b608bd8-92a9-4ef3-b9af-f6214ce84598' User entered '09 Dec 2020 12:48:42'	System	09 Dec 2020 17:48:45
	System	09 Dec 2020 17:48:45



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-16T09:52:07', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a75a11c0-8371-453d-beac-9ed2b0ac06b9' User entered 'No (N)'	System	16 Dec 2020 14:52:30
	System	16 Dec 2020 14:52:30



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-16T09:52:14', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a75a11c0-8371-453d-beac-9ed2b0ac06b9' User entered 'No (N)'	System	16 Dec 2020 14:52:30
	System	16 Dec 2020 14:52:30



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-16T09:52:28', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a75a11c0-8371-453d-beac-9ed2b0ac06b9' User entered '16 Dec 2020 09:52:28'	System	16 Dec 2020 14:52:30
	System	16 Dec 2020 14:52:30



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-23T10:05:40', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'e2c2bb99-4d7b-4b69-9f7d-87749e0ebc5d' User entered 'No (N)'	System	23 Dec 2020 15:05:59
	System	23 Dec 2020 15:05:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-23T10:05:50', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'e2c2bb99-4d7b-4b69-9f7d-87749e0ebc5d' User entered 'No (N)'	System	23 Dec 2020 15:05:59
	System	23 Dec 2020 15:05:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-23T10:05:54', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'e2c2bb99-4d7b-4b69-9f7d-87749e0ebc5d' User entered '23 Dec 2020 10:05:54'	System	23 Dec 2020 15:05:59
	System	23 Dec 2020 15:05:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-30T10:22:59', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '85a8a777-c916-4120-823e-01c8cdac4c15' User entered 'No (N)'	System	30 Dec 2020 16:23:22
	System	30 Dec 2020 16:23:22



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-30T10:23:06', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '85a8a777-c916-4120-823e-01c8cdac4c15' User entered 'No (N)'	System	30 Dec 2020 16:23:22



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2020-12-30T10:23:16', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '85a8a777-c916-4120-823e-01c8cdac4c15' User entered '30 Dec 2020 10:23:16'	System	30 Dec 2020 16:23:22
	System	30 Dec 2020 16:23:22



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-06T09:01:31', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '09ef8244-4d9b-4bbe-a53e-470a01cf80b0' User entered 'Yes (Y)'	System	06 Jan 2021 14:02:31
	System	06 Jan 2021 14:02:31



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-06T09:01:37', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '09ef8244-4d9b-4bbe-a53e-470a01cf80b0' User entered 'No (N)'	System	06 Jan 2021 14:02:31



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-06T09:01:44', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '09ef8244-4d9b-4bbe-a53e-470a01cf80b0' User entered 'No (N)'	System	06 Jan 2021 14:02:31



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-06T09:01:52', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '09ef8244-4d9b-4bbe-a53e-470a01cf80b0' User entered 'Yes (Y)'	System	06 Jan 2021 14:02:31
	System	06 Jan 2021 14:02:31



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-06T09:02:03', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '09ef8244-4d9b-4bbe-a53e-470a01cf80b0'	System	06 Jan 2021 14:02:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 14:02:31



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-06T09:02:23', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '09ef8244-4d9b-4bbe-a53e-470a01cf80b0' User entered '06 Jan 2021 09:02:23'	System	06 Jan 2021 14:02:31
	System	06 Jan 2021 14:02:31



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-13T11:08:25', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '14766fbf-e393-4a8f-a60e-35535ce1c1b4'	System	13 Jan 2021 16:08:44
User entered 'No (N)'	System	13 Jan 2021 16:08:44



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-13T11:08:34', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '14766fbf-e393-4a8f-a60e-35535ce1c1b4'	System	13 Jan 2021 16:08:44
User entered 'No (N)'	System	13 Jan 2021 16:08:44



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-13T11:08:41', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '14766fbf-e393-4a8f-a60e-35535ce1c1b4' User entered '13 Jan 2021 11:08:41'	System	13 Jan 2021 16:08:44
	System	13 Jan 2021 16:08:44



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-21T10:59:09', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c7564037-530a-4f28-932f-1c5b65b04348' User entered 'No (N)'	System	21 Jan 2021 15:59:28
	System	21 Jan 2021 15:59:28



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-21T10:59:13', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c7564037-530a-4f28-932f-1c5b65b04348' User entered 'No (N)'	System	21 Jan 2021 15:59:28



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-21T10:59:23', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'c7564037-530a-4f28-932f-1c5b65b04348' User entered '21 Jan 2021 10:59:23'	System	21 Jan 2021 15:59:28
	System	21 Jan 2021 15:59:28



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-27T08:25:44', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '91c32f2c-1012-480b-a4d7-4244c0c2180d' User entered 'No (N)'	System	27 Jan 2021 13:26:04
	System	27 Jan 2021 13:26:04



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-27T08:25:50', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '91c32f2c-1012-480b-a4d7-4244c0c2180d' User entered 'No (N)'	System	27 Jan 2021 13:26:04
	System	27 Jan 2021 13:26:04



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-01-27T08:25:58', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '91c32f2c-1012-480b-a4d7-4244c0c2180d' User entered '27 Jan 2021 08:25:58'	System	27 Jan 2021 13:26:04
	System	27 Jan 2021 13:26:04



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-03T09:56:41', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd85ba560-b1fc-42ff-bc0f-c84ee7146031' User entered 'No (N)'	System	03 Feb 2021 15:57:01
	System	03 Feb 2021 15:57:01



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-03T09:56:53', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd85ba560-b1fc-42ff-bc0f-c84ee7146031' User entered 'No (N)'	System	03 Feb 2021 15:57:01
	System	03 Feb 2021 15:57:01



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-03T09:56:58', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd85ba560-b1fc-42ff-bc0f-c84ee7146031'	System	03 Feb 2021 15:57:01
User entered '03 Feb 2021 09:56:58'	System	03 Feb 2021 15:57:01



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-10T19:23:54', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'e452fdcd-5e2b-42be-9468-2dd9aaef9aa2'	System	11 Feb 2021 00:26:12
User entered 'No (N)'	System	11 Feb 2021 00:26:12



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-10T19:24:13', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'e452fdcd-5e2b-42be-9468-2dd9aaef9aa2'	System	11 Feb 2021 00:26:12
User entered 'No (N)'	System	11 Feb 2021 00:26:12



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-10T19:24:20', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'e452fdcd-5e2b-42be-9468-2dd9aaef9aa2' User entered '10 Feb 2021 19:24:20'	System	11 Feb 2021 00:26:12
	System	11 Feb 2021 00:26:12



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-17T07:20:54', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '14f5cf0b-7293-42a0-8e7f-d406fbc7b7e7' User entered 'No (N)'	System	17 Feb 2021 12:21:17
	System	17 Feb 2021 12:21:17



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-17T07:21:05', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '14f5cf0b-7293-42a0-8e7f-d406fbc7b7e7'	System	17 Feb 2021 12:21:17
User entered 'No (N)'	System	17 Feb 2021 12:21:17



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-17T07:21:12', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '14f5cf0b-7293-42a0-8e7f-d406fbc7b7e7' User entered '17 Feb 2021 07:21:12'	System	17 Feb 2021 12:21:17
	System	17 Feb 2021 12:21:17



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-24T14:36:39', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a6200cf9-26a9-4082-bdbe-d51172900576' User entered 'No (N)'	System	24 Feb 2021 20:36:59
	System	24 Feb 2021 20:36:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-24T14:36:44', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a6200cf9-26a9-4082-bdbe-d51172900576' User entered 'No (N)'	System	24 Feb 2021 20:36:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-02-24T14:36:56', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'a6200cf9-26a9-4082-bdbe-d51172900576' User entered '24 Feb 2021 14:36:56'	System	24 Feb 2021 20:36:59
	System	24 Feb 2021 20:36:59



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-04T13:02:07-06:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '07c36aac-8b5f-4f59-aa92-ddcaa9add5cb' User entered 'No (N)'	System	04 Mar 2021 19:02:27
	System	04 Mar 2021 19:02:27



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-04T13:02:15-06:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '07c36aac-8b5f-4f59-aa92-ddcaa9add5cb'	System	04 Mar 2021 19:02:27
User entered 'No (N)'	System	04 Mar 2021 19:02:27



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-04T13:02:21-06:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '07c36aac-8b5f-4f59-aa92-ddcaa9add5cb' User entered '04 Mar 2021 13:02:21'	System	04 Mar 2021 19:02:27
	System	04 Mar 2021 19:02:27



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-10T07:39:53-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd868e351-b363-4b79-b679-b418062fcc31'	System	10 Mar 2021 12:40:15
User entered 'No (N)'	System	10 Mar 2021 12:40:15



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-10T07:40:01-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd868e351-b363-4b79-b679-b418062fcc31'	System	10 Mar 2021 12:40:15
User entered 'No (N)'	System	10 Mar 2021 12:40:15



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-10T07:40:12-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'd868e351-b363-4b79-b679-b418062fcc31'	System	10 Mar 2021 12:40:15
User entered '10 Mar 2021 07:40:12'	System	10 Mar 2021 12:40:15



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-17T07:29:49-04:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '0360de77-dcd6-42fb-a85d-609027807c0a'	System	17 Mar 2021 11:30:06
User entered 'No (N)'	System	17 Mar 2021 11:30:06



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-17T07:29:56-04:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '0360de77-dcd6-42fb-a85d-609027807c0a' User entered 'No (N)'	System	17 Mar 2021 11:30:06
	System	17 Mar 2021 11:30:06



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-17T07:30:03-04:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '0360de77-dcd6-42fb-a85d-609027807c0a' User entered '17 Mar 2021 07:30:03'	System	17 Mar 2021 11:30:06
	System	17 Mar 2021 11:30:06



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-25T07:32:31-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '839a7824-8013-4919-a8b4-d436086851ac'	System	25 Mar 2021 12:33:03
User entered 'No (N)'	System	25 Mar 2021 12:33:03



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-25T07:32:37-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '839a7824-8013-4919-a8b4-d436086851ac'	System	25 Mar 2021 12:33:03
User entered 'No (N)'	System	25 Mar 2021 12:33:03



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-25T07:32:58-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '839a7824-8013-4919-a8b4-d436086851ac'	System	25 Mar 2021 12:33:03
User entered '25 Mar 2021 07:32:58'	System	25 Mar 2021 12:33:03



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-31T16:15:40-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b58e9c75-352d-4193-9cb1-e95a7cdf6f99'	System	31 Mar 2021 21:15:58
User entered 'No (N)'	System	31 Mar 2021 21:15:58



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-31T16:15:50-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b58e9c75-352d-4193-9cb1-e95a7cdf6f99'	System	31 Mar 2021 21:15:58
User entered 'No (N)'	System	31 Mar 2021 21:15:58



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-31T16:15:55-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: 'b58e9c75-352d-4193-9cb1-e95a7cdf6f99'	System	31 Mar 2021 21:15:58
User entered '31 Mar 2021 16:15:55'	System	31 Mar 2021 21:15:58



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-07T09:21:31-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '099c049f-3231-44c9-870e-98622c1ed304'	System	07 Apr 2021 14:21:43
User entered 'No (N)'	System	07 Apr 2021 14:21:43



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-07T09:21:35-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '099c049f-3231-44c9-870e-98622c1ed304'	System	07 Apr 2021 14:21:43
User entered 'No (N)'	System	07 Apr 2021 14:21:43



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-07T09:21:39-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '099c049f-3231-44c9-870e-98622c1ed304'	System	07 Apr 2021 14:21:43
User entered '07 Apr 2021 09:21:39'	System	07 Apr 2021 14:21:43



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-16T09:11:39-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bc25714-12cd-44e0-bb6d-0a9c70712eb6'	System	16 Apr 2021 14:11:58
User entered 'No (N)'	System	16 Apr 2021 14:11:58



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-16T09:11:48-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bc25714-12cd-44e0-bb6d-0a9c70712eb6'	System	16 Apr 2021 14:11:58
User entered 'No (N)'	System	16 Apr 2021 14:11:58



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-16T09:11:53-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2bc25714-12cd-44e0-bb6d-0a9c70712eb6'	System	16 Apr 2021 14:11:58
User entered '16 Apr 2021 09:11:53'	System	16 Apr 2021 14:11:58



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-22T14:12:08-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3d80123a-76f0-4410-9135-662da8b8eb24' User entered 'No (N)'	System	22 Apr 2021 19:12:19
	System	22 Apr 2021 19:12:19



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-22T14:12:01-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3d80123a-76f0-4410-9135-662da8b8eb24'	System	22 Apr 2021 19:12:19
User entered 'No (N)'	System	22 Apr 2021 19:12:19



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-22T14:12:15-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '3d80123a-76f0-4410-9135-662da8b8eb24'	System	22 Apr 2021 19:12:19
User entered '22 Apr 2021 14:12:15'	System	22 Apr 2021 19:12:19



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-28T15:06:26-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8b701fdc-a6b6-49b1-bf46-780ee7ea3e83'	System	29 Apr 2021 00:23:32
User entered 'No (N)'	System	29 Apr 2021 00:23:32



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-28T15:06:30-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8b701fdc-a6b6-49b1-bf46-780ee7ea3e83'	System	29 Apr 2021 00:23:32
User entered 'No (N)'	System	29 Apr 2021 00:23:32



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-04-28T15:06:43-05:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '8b701fdc-a6b6-49b1-bf46-780ee7ea3e83'	System	29 Apr 2021 00:23:32
User entered '28 Apr 2021 15:06:43'	System	29 Apr 2021 00:23:32



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:58:33



**US3312249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:58:33
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:58:33



US3312249

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:57:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-01T09:12:28-06:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2970db13-e6a8-47fc-b516-bd6ec694705c' User entered 'No (N)'	System	01 Mar 2021 15:12:40
	System	01 Mar 2021 15:12:40



**US3312249**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8402145D-FBB9-4BA0-86C9-EB2340D93C74)', Time: '2021-03-01T09:12:38-06:00', User OID: 'PatientReportedOutcome (US3312249)', ODM File OID: '2970db13-e6a8-47fc-b516-bd6ec694705c' User entered '01 Mar 2021 15:12:38'	System	01 Mar 2021 15:12:40
	System	01 Mar 2021 15:12:40



**US3312249**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:44



**US3312249**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:44



**US3312249**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:44



**US3312249**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:44



**US3312249**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:50



**US3312249**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:18
User entered 'I'	System	24 Nov 2020 14:25:50



**US3312249**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:03:47



**US3312249**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:03:47



**US3312249**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:03:47



**US3312249**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:03:47



**US3312249**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:03:55



**US3312249**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered 'I'	System	29 Dec 2020 15:03:55



**US3312249**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:10:46



**US3312249**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:10:46



**US3312249**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:10:46



**US3312249**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:10:46



**US3312249**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:10:49



**US3312249**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered 'I'	System	27 Jan 2021 19:10:49



**US3312249**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4)	27 Feb 2021 00:25:21
	Karol Moore (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '26 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Feb 2021 00:25:21



**US3312249**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Feb 2021 00:25:21



**US3312249**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4)	27 Feb 2021 00:25:21
	Karol Moore (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	27 Feb 2021 00:25:24



**US3312249**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered 'I'	System	27 Feb 2021 00:25:24



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:03



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:03



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:03



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered 'VISIT4'	System	30 Mar 2021 19:42:03



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered empty.	System	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered empty.	System	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered empty.	System	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered empty.	System	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered empty.	System	30 Mar 2021 19:42:09



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:23



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:57:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:23



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:30



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:30



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '09:16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:30



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered '30 Mar 2021 09:16'	System	30 Mar 2021 19:42:30



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:42:34



**US3312249**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:14:00
User entered 'I'	System	30 Mar 2021 19:42:34



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:17



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '02 Feb 2021'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:17



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Clinic (Clinic)'	(b) (4) Monica Atwood (b) (4) (b) (4)	06 Feb 2021 19:53:17



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User entered 'UNBLND_DECIDE'	System	06 Feb 2021 19:53:17



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '02 Feb 2021'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:50:15



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:50:15



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '02 Feb 2021'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User entered empty.	System	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User entered empty.	System	06 Feb 2021 19:53:40



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:55:52



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '02 Feb 2021'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:55:52



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '09:07'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:55:52



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User entered '02 Feb 2021 09:07'	System	06 Feb 2021 19:55:52



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:57:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:56:03



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '02 Feb 2021'	(b) (4) Monica Atwood (b) (4)	06 Feb 2021 19:56:03



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:57:13**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '09:06'	(b) (4)	06 Feb 2021 19:56:03
	Monica Atwood (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:54
User entered '02 Feb 2021 09:06'	System	06 Feb 2021 19:56:03



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:22



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:22



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:22



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:22



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:22



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '16:24'	(b) (4)	10 Sep 2020 00:19:43
	Karol Moore (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User entered '24 Aug 2020 16:24'	System	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User entered 'bpm'	System	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User entered 'breaths/min'	System	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '132'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User entered 'mmHg'	System	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '76'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
User entered 'mmHg'	System	10 Sep 2020 00:19:43



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39



**US3312249**

**Folder: Unscheduled 24 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 16:57:13**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:47:08
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:53:07
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:25:44



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18



US3312249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User closed query 'Per CDM: Please clarify and update CM form if subject took any medications for this AE. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 07:40:12
Query 'Per CDM: Please clarify and update CM form if subject took any medications for this AE. Thank you!' answered with 'no medications taken' (Site from DM).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:10:42
User opened query 'Per CDM: Please clarify and update CM form if subject took any medications for this AE. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:00:38
User closed query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right Arm, Left Arm, etc.) and type (i.e., Urticarial or Non-Urticarial) of INJECTION SITE RASH. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:00:04
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site rash, LLT: Injection site rash - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Oct 2020 22:12:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Oct 2020 22:12:28
Data point term sent to Coder	System	18 Oct 2020 22:11:12
Query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right Arm, Left Arm, etc.) and type (i.e., Urticarial or Non-Urticarial) of INJECTION SITE RASH. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated per source' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:10:46
Coding entries removed.	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:10:39
User entered 'left INJECTION SITE RASH' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:10:39

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EAB) (1725)

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US3312249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right Arm, Left Arm, etc.) and type (i.e., Urticarial or Non-Urticarial) of INJECTION SITE RASH. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:15:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site rash, LLT: Injection site rash - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	10 Sep 2020 00:27:43
Data point term sent to Coder	System	10 Sep 2020 00:27:25
User entered 'INJECTION SITE RASH'	Karol Moore (b) (4)	10 Sep 2020 00:26:25
	(b) (4)	



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4)	10 Sep 2020 00:26:25
	Karol Moore (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User entered empty.	System	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '04 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User entered empty.	System	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4)	10 Sep 2020 00:26:25
	Karol Moore (b) (4)	
	(b) (4)	



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User entered '0'	System	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18
User entered '0'	System	10 Sep 2020 00:26:25



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:18



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24



US3312249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastrointestinal infection, LLT: Gastrointestinal infection - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:17:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:17:36
Data point term sent to Coder	System	21 Oct 2020 14:13:32
User entered 'intestinal infection'	Karol Moore (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User entered empty.	System	21 Oct 2020 14:12:50



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 11:02:01
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	21 Dec 2020 17:29:48
User entered 'No (N)' reason for change: New Information	Monica Atwood (b) (4) (b) (4)	21 Dec 2020 17:29:38
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:52:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '03 Oct 2020' reason for change: New Information	(b) (4)	21 Dec 2020 17:29:38
User entered empty.	Monica Atwood (b) (4)	21 Oct 2020 14:12:50
	(b) (4)	



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User entered empty.	System	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Karol Moore (b) (4)	21 Oct 2020 14:12:50



US3312249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 14:12:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 14:12:57
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Oct 2020 14:12:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 14:12:50
User entered empty.	System	21 Oct 2020 14:12:50
	Karol Moore (b) (4)	21 Oct 2020 14:12:50
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'None (NONE)'	(b) (4)	21 Oct 2020 14:12:50
	Karol Moore (b) (4)	
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Monica Atwood (b) (4)	21 Dec 2020 17:29:38
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Karol Moore (b) (4)	21 Oct 2020 14:12:50
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User entered '0'	System	21 Oct 2020 14:12:57



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24
User entered 'I'	System	21 Oct 2020 14:12:50



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:24



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 18:15:57
User entered 'USA-US300-2021-mRNA-1273-P301000004'	System	08 Jan 2021 18:15:51
User entered 'New'	(b) (4), (b) (6)	08 Jan 2021 18:15:51



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 23:48:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 23:48:26
Data point term sent to Coder	System	07 Apr 2021 23:47:58
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 23:47:50
	(b) (4), (b) (6)	
User entered 'left lower extremity deep vein thrombosis' reason for change: Data Entry Error		07 Apr 2021 23:47:50
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Venous thrombosis limb, LLT: Leg venous thrombosis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Jan 2021 18:50:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Jan 2021 18:50:42
	(b) (4)	
Data point term sent to Coder	System	08 Jan 2021 02:40:11
User entered 'left calf venous thrombosis'	(b) (4), (b) (6)	08 Jan 2021 02:40:08



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	08 Jan 2021 02:43:32
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	08 Jan 2021 02:43:32
User entered '02 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 02:43:32
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Jan 2021 02:43:08
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	08 Jan 2021 02:43:08
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Jan 2021 02:43:08
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	08 Jan 2021 02:43:08
User entered '02 Jan 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 02:43:08



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Jan 2021 02:40:08
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		08 Jan 2021 02:40:08
User entered '20 Jan 2020'	(b) (4), (b) (6)	08 Jan 2021 02:40:08



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 02:40:08



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	08 Apr 2021 17:13:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:13:18
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	08 Apr 2021 17:11:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 02:40:08



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Apr 2021 17:13:18
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Apr 2021 17:13:18
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Apr 2021 17:11:31
User entered '01 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:11:31
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 02:40:08



US3312249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:21:30
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:13:24
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 15:15:34
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:21:35
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:13:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:13:18
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 15:15:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	08 Jan 2021 02:40:08



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 15:58:43



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
User entered '66 YEAR OLD MAN DEVELOPED LEFT CALF PAIN WITH MINIMAL TO NO SWELLING 02JAN2021 FOR WHICH HE VISITED ER. ULTRASOUND REVEALED DEEP VENOUS THROMBOSIS. SUBJECT WAS DISCHARGED TO HOME SAME DAY ON XARELTO AND HE BELIEVES HE RECEIVED NO OTHER MEDS. HE REPORTS TRAVELLING BOTH BY AUTOMOBILE AND PLANE SEVERAL TIMES BACK AND FORTH TO FLORIDA FROM KANSAS CITY OVER LAST FEW MONTHS AND INCREASED SEDENTARY LIFESTYLE DUE TO RECENT CHANGE FROM HOUSE TO APARTMENT. THE ER ADVISED HIM THAT IN HIS CASE THERE WERE NO TRAVEL CONCERNS OR RESTRICTIONS RELATED TO THE CLOT, AND THAT HE COULD RESUME NORMAL ACTIVITY INCLUDING MODERATE EXERCISE IMMEDIATELY. HE WAS ADVISED BY ER AND NOW BY ME TO IMMEDIATELY SEEK MEDICAL ATTENTION SHOULD ANY SYMPTOMS OF PE APPEAR. HE SOUNDS WELL OVER THE PHONE, REPORTS THAT HE IS TOLERATING EXERCISE NORMALLY, AND THAT PAIN IS IMPROVED. HE DENIES SWELLING. WILL GET MED RECORDS.F/U 22JAN2021 MR CONSISTENT WITH ORIGINAL REPORT THAT AFTER APPROXIMATELY A DAY OR SO OF LEFT CALF PAIN SUBJECT VISITED ER ON 04JAN21 WITH CONCERN FOR DVT. HE WAS CORRECT; ULTRASOUND REVEALED OCCLUSIVE THROMBUS WITHIN THE DISTAL POPLITEAL AND A POSTERIOR TIBIAL VEIN AND NON-OCCLUSIVE THROMBUS WITHIN THE PROXIMAL POPLITEAL, A POSTERIOR TIBIAL, AND THE PERONEAL VEINS. THERE WAS NO SWELLING OF THE EXTREMITY, NO SHORTNESS OF AIR, AND NO SYMPTOMS OF COVID-19. PT, PTT, INR WERE WNL. COVID	(b) (4), (b) (6)	08 Apr 2021 17:12:48



US3312249

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
TEST WAS NOT DONE. SUBJECT HAS HISTORY OF HTN AND BP WAS IN THE 180'S AND THEN 170'S SYSTOLIC. HE WAS STARTED ON XARELTO 15MG PO BID AND DISCHARGED TO HOME. ON PHONE CALL THIS AM 22JAN21 SUBJECT SOUNDS WELL AND VIBRANT, REPORTS HE FEELS WELL ON XARELTO, AND DENIES SHORTNESS OF AIR AND LOWER EXTREMITY SWELLING OR DISCOMFORT. HE HAS NOT HAD A RECENT COVID TEST AND IS OUT OF STATE 04/08/21 F/U: US done 04/01/21-no evidence of clot, continues Xarelto prophylactically 3 more mos.AE closed' reason for change: Data Entry Error		
User closed query 'Per DM CLR: Narrative = PT, PTT, INR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:05:15
User closed query 'Per DM CLR: Narrative indicates that the subject had Ultrasound. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:05:05
Query 'Per DM CLR: Narrative indicates that the subject had Ultrasound. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'NA-diagnostic test not procedrue' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:15:06
Query 'Per DM CLR: Narrative = PT, PTT, INR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'NA, labs not procedures-diagnostic' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:14:55
User opened query 'Per DM CLR: Narrative = PT, PTT, INR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:41:36



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject had Ultrasound. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:21:23



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
User entered '66 YEAR OLD MAN DEVELOPED LEFT CALF PAIN WITH MINIMAL TO NO SWELLING 02JAN2021 FOR WHICH HE VISITED ER. ULTRASOUND REVEALED DEEP VENOUS THROMBOSIS. SUBJECT WAS DISCHARGED TO HOME SAME DAY ON XARELTO AND HE BELIEVES HE RECEIVED NO OTHER MEDS. HE REPORTS TRAVELLING BOTH BY AUTOMOBILE AND PLANE SEVERAL TIMES BACK AND FORTH TO FLORIDA FROM KANSAS CITY OVER LAST FEW MONTHS AND INCREASED SEDENTARY LIFESTYLE DUE TO RECENT CHANGE FROM HOUSE TO APARTMENT. THE ER ADVISED HIM THAT IN HIS CASE THERE WERE NO TRAVEL CONCERNS OR RESTRICTIONS RELATED TO THE CLOT, AND THAT HE COULD RESUME NORMAL ACTIVITY INCLUDING MODERATE EXERCISE IMMEDIATELY. HE WAS ADVISED BY ER AND NOW BY ME TO IMMEDIATELY SEEK MEDICAL ATTENTION SHOULD ANY SYMPTOMS OF PE APPEAR. HE SOUNDS WELL OVER THE PHONE, REPORTS THAT HE IS TOLERATING EXERCISE NORMALLY, AND THAT PAIN IS IMPROVED. HE DENIES SWELLING. WILL GET MED RECORDS.F/U 22Jan2021 MR consistent with original report that after approximately a day or so of left calf pain subject visited ER on 04Jan21 with concern for DVT. He was correct; ultrasound revealed occlusive thrombus within the distal popliteal and a posterior tibial vein and non-occlusive thrombus within the proximal popliteal, a posterior tibial, and the peroneal veins. There was no swelling of the extremity, no shortness of air, and no symptoms of Covid-19. PT, PTT, INR were WNL. Covid test was not done. Subject has history of HTN and BP was in the 180's and then 170's systolic. He was started on Xarelto 15mg po bid and discharged to home. On phone call this am 22Jan21 subject sounds well and vibrant,	(b) (4), (b) (6)	23 Jan 2021 00:03:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
reports he feels well on Xarelto, and denies shortness of air and lower extremity swelling or discomfort. He has not had a recent Covid test and is out of state' reason for change: Data Entry Error		
User entered '66 year old man developed left calf pain with minimal to no swelling 02Jan2021 for which he visited ER. Ultrasound revealed deep venous thrombosis. Subject was discharged to home same day on Xarelto and he believes he received no other meds. He reports travelling both by automobile and plane several times back and forth to Florida from Kansas City over last few months and increased sedentary lifestyle due to recent change from house to apartment. The ER advised him that in his case there were no travel concerns or restrictions related to the clot, and that he could resume normal activity including moderate exercise immediately. He was advised by ER and now by me to immediately seek medical attention should any symptoms of PE appear. He sounds well over the phone, reports that he is tolerating exercise normally, and that pain is improved. He denies swelling. Will get med records'	(b) (4), (b) (6)	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 02:40:08



**US3312249**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 02:40:08



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 16:57:13**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:47:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:21:51



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 00:22:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:22:48
Data point term sent to Coder	System	10 Sep 2020 00:22:19
User entered 'pRAVASTATIN'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:22:16



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'HYPERLIPIDEMIA'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '20'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2000'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:22:16
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:22:16



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:22:16



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:22:16



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 00:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:24:51
Data point term sent to Coder User entered 'LOSARTAN'	System Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:23:20 10 Sep 2020 00:22:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'HYPERTENSION'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '50'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2017'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:22:36
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:22:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:22:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:22:36



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 00:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:24:51
Data point term sent to Coder	System	10 Sep 2020 00:23:21
User entered 'PROPRANOLOL ER'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:23:00



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'HYPERTENSION'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '80'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2017'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:23:00
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:23:00



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:23:00



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:23:00



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 00:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 00:25:52
Data point term sent to Coder	System	10 Sep 2020 00:24:21
User entered 'PANTOPRAZOLE'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:23:23



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '40'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2000'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:23:23
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:23:23



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:23:23



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:23:23



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 00:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:25:52
Data point term sent to Coder	System	10 Sep 2020 00:24:22
User entered 'acetylsalicylic acid'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 00:23:47



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'CARDIAC PROPHYLAXIS'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '81'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2000'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:23:47
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:23:47



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:23:47



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:23:47



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 00:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 00:25:52
Data point term sent to Coder	System	10 Sep 2020 00:24:21
User entered 'Coenzyme Q10'	Karol Moore (b) (4)	10 Sep 2020 00:24:18



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'HEALTH MAINTENANCE'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '100'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2012'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:24:18
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:24:18



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:24:18



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:24:18



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 00:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 00:25:52
Data point term sent to Coder	System	10 Sep 2020 00:25:23
User entered 'MULTIVITAMIN'	Karol Moore (b) (4)	10 Sep 2020 00:24:40



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'HEALTH MAINTENANCE'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '1'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'tablet (TABLET)'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2000'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:24:40
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:24:40



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:24:40



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:24:40



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ASCOPHYLLUM NODOSUM;ASCORBIC ACID;BETACAROTENE;BORAGO OFFICINALIS;CAPSICUM ANNUUM;PETROSELINUM CRISPUM;PYRIDOXINE HYDROCHLORIDE;SERENOA REPENS;TOCOPHERYL ACETATE;ZEA MAYS STYLE;ZINC OXIDE, PRODUCTSYNONYM: PROSTATA PLUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 12:32:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 12:32:39
Data point term sent to Coder	System	10 Sep 2020 00:25:22
User entered 'PROSTATE PLUS'	Karol Moore (b) (4)	10 Sep 2020 00:25:04



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'HEALTH MAINTENANCE'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '1'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'tablet (TABLET)'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2016'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:25:04
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:25:04



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:25:04



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:25:04



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN SULFATE;GLUCOSAMINE;METHYLSULFONY LMETHANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 05:51:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 05:51:09
Data point term sent to Coder	System	13 Nov 2020 15:10:30
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	13 Nov 2020 15:09:47
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'UPDATED' (Site from System).	Karol Moore (b) (4)	13 Nov 2020 15:09:47
User entered 'FLEX 1 (GLUCOSAMINE 750MG/CHONDROITIN SULFATE 400MG/ METHYLSUFONYLMETHANE 375MG)' reason for change: Data Entry Error	Karol Moore (b) (4)	13 Nov 2020 15:09:34
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	17 Sep 2020 10:14:50
Data point term sent to Coder	System	14 Sep 2020 23:07:32
Data point term sent to Coder	System	10 Sep 2020 00:26:24
User entered 'FLEX 1'	Karol Moore (b) (4)	10 Sep 2020 00:25:32



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	Monica Atwood (b) (4)	14 Sep 2020 23:07:03
	(b) (4)	
User entered 'OSTEOPOROSIS'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '1'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'tablet (TABLET)'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'UN UNK 2015'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	10 Sep 2020 00:25:32
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:25:32



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 00:25:32



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 00:25:32



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 05:11:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 05:11:35
Data point term sent to Coder	System	18 Oct 2020 22:08:10
User entered 'sulfamethoxazole/trimethoprim'	Karol Moore (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User closed query 'Per DM CLR: Please update the condition to include the type and location of INTESTINAL INFECTION (e.g. etiology of infection, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:50:18
Query 'Per DM CLR: Please update the condition to include the type and location of INTESTINAL INFECTION (e.g. etiology of infection, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'EXACT ETIOLOGY UNKNOWN.POSSIBLY RELATED TO PANTOPRAZOLE' (Site from DM).	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:44:36
User opened query 'Per DM CLR: Please update the condition to include the type and location of INTESTINAL INFECTION (e.g. etiology of infection, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:36:43
User entered 'intestinal infection'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:46:31
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:35:47
User entered '800/160' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:35:43
User entered '160' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:10:49
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:36:29
User entered '160/11'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'twice daily (BID)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '23 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:02:04
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	06 Feb 2021 20:05:17
User entered 'No (N)' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	06 Feb 2021 20:04:44
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:23:44
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4)	06 Feb 2021 20:04:44
User entered empty.	Monica Atwood (b) (4)	18 Oct 2020 22:07:21
	(b) (4)	



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User entered '2'	System	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User entered '1'	System	18 Oct 2020 22:07:21



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:36
User entered '804 (804)'	System	18 Oct 2020 22:07:21



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OTHER DRUGS FOR CONSTIPATION, PRODUCT: LINACLOTIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 05:10:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 05:10:14
Data point term sent to Coder	System	18 Oct 2020 22:08:10
User entered 'linacotide'	Karol Moore (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 14:13:10
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'SUBJECT GIVEN MEDICATION FOR SYMPTOMS OF BLOATING, GAS, ABDOMINAL DISCOMFORT AND IRREGULAR STOOLS. LATER DIAGNOSIS CONFIRMED FOR ABOVE SYMPTOMS TO BE SMALL BOWEL BACTERIAL OVERGROWTH.' (Site from DM).	Monica Atwood (b) (4) (b) (4)	21 Dec 2020 17:24:12
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 14:55:51
User entered 'small bowel bacterial overgrowth'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '145'	Karol Moore (b) (4)	18 Oct 2020 22:07:59



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (145 mg) of this medication. Please review dose and dose unit and update as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:04:40
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (145 mg) of this medication. Please review dose and dose unit and update as applicable. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:34:45
User entered 'ug (ug)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	13 Nov 2020 15:34:40
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (145 mg) of this medication. Please review dose and dose unit and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:37:02
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'once daily (QD)'	Karol Moore (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '18 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User entered '1'	System	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User entered '1'	System	18 Oct 2020 22:07:59



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:39
User entered '804 (804)'	System	18 Oct 2020 22:07:59



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 22:09:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 22:09:28
Data point term sent to Coder User entered 'ibuprofen'	System Karol Moore (b) (4)	18 Oct 2020 22:09:11 18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'muscle aches/joint aches'	Karol Moore (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '400'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mg (mg)'	Karol Moore (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	Karol Moore (b) (4)	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User entered empty.	System	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User entered empty.	System	18 Oct 2020 22:08:36



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:43
User entered empty.	System	18 Oct 2020 22:08:36



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 22:09:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 22:09:28
Data point term sent to Coder User entered 'ibuprofen'	System Karol Moore (b) (4)	18 Oct 2020 22:09:11 18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'muscle aches/joint aches'	Karol Moore (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '400'	Karol Moore (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '03 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	Karol Moore (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '03 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	Karol Moore (b) (4)	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User entered empty.	System	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User entered empty.	System	18 Oct 2020 22:09:09



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:47
User entered empty.	System	18 Oct 2020 22:09:09



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:42:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:42:27
Data point term sent to Coder	System	28 Oct 2020 14:32:20
User entered 'seasonal influenza vaccine'	Karol Moore (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'seasonal influenza vaccine'	Karol Moore (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0.5' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:38
User entered '1'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:38
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:38
User entered 'injection'	Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Intramuscular (INTRAMUSCULAR)'	Karol Moore (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '25 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '25 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User entered empty.	System	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User entered empty.	System	28 Oct 2020 14:32:14



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:51
User entered empty.	System	28 Oct 2020 14:32:14



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 02:46:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 02:46:33
Data point term sent to Coder	System	08 Jan 2021 02:46:14
Coding entries removed.	(b) (4), (b) (6)	08 Jan 2021 02:45:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 02:45:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 02:45:33
Data point term sent to Coder	System	08 Jan 2021 02:45:14
User entered 'xarelto'	(b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'left calf venous thrombosis'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '15'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:51:25
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 02:45:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 02:45:13
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 02:45:13
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 02:44:46
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Jan 2021 02:45:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 02:45:53
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 02:45:53
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 02:44:46
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:47
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User entered '2'	System	30 Mar 2021 19:51:25
User entered '1'	System	08 Jan 2021 02:45:13
User entered empty.	System	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User entered '1'	System	08 Jan 2021 02:45:13
User entered empty.	System	08 Jan 2021 02:44:46



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:02:57
User entered '804 (804)'	System	08 Jan 2021 02:45:13
User entered empty.	System	08 Jan 2021 02:44:46



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 19:52:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 19:52:11
Data point term sent to Coder	System	30 Mar 2021 19:51:16
User entered 'xarelto'	(b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'left calf venous thrombosis'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '20'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



US3312249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Mar 2021 19:50:26



**US3312249**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:57:13**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 17:52:57



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'USA-US300-2021-MRNA-1273-P301000004'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Carlos'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Fierro'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '16300 College Blvd'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Shawnee'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'KS'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '66219'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:04:33
User entered 'US'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 13:23:18
User entered '3'	System	08 Apr 2021 16:08:30
User entered '2'	System	25 Jan 2021 19:04:46
User entered '1'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'USA-US300-2021-MRNA-1273-P301000004'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Carlos'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Fierro'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '16300 College Blvd'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Shawnee'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'KS'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '66219'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:04:33
User entered 'US'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 13:23:18
User entered '3'	System	08 Apr 2021 16:08:30
User entered '2'	System	25 Jan 2021 19:04:46
User entered '1'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '08/Jan/2021 13:16'	(b) (4) System	08 Jan 2021 18:16:14



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:57:13

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 19:04:33
User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'USA-US300-2021-MRNA-1273-P301000004'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Carlos'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Fierro'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '16300 College Blvd'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Shawnee'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'KS'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '66219'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:04:33
User entered 'US'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 13:23:18
User entered '3'	System	08 Apr 2021 16:08:30
User entered '2'	System	25 Jan 2021 19:04:46
User entered '1'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered '25/Jan/2021 19:04'	(b) (4) System	25 Jan 2021 19:04:46



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:57:13

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:08:21
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:04:46



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'USA-US300-2021-MRNA-1273-P301000004'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Carlos'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Fierro'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '16300 College Blvd'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Shawnee'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'KS'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '66219'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:04:33
User entered 'US'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 13:23:18
User entered '3'	System	08 Apr 2021 16:08:30
User entered '2'	System	25 Jan 2021 19:04:46
User entered '1'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 16:15:45
User entered '08/Apr/2021 12:08'	(b) (4) System	08 Apr 2021 16:08:30



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:57:13

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:22:47
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 16:15:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:08:30



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'USA-US300-2021-MRNA-1273-P301000004'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'No (N)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Yes (Y)'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Carlos'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Fierro'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '16300 College Blvd'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'Shawnee'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered 'KS'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:16:06
User entered '66219'	System	08 Jan 2021 18:15:51



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:33:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:04:33
User entered 'US'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Apr 2021 13:23:18
User entered '3'	System	08 Apr 2021 16:08:30
User entered '2'	System	25 Jan 2021 19:04:46
User entered '1'	System	08 Jan 2021 18:16:14



**US3312249**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered '09/Apr/2021 09:23'	(b) (4) System	09 Apr 2021 13:23:18



US3312249

Folder: SAE USA-US300-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:57:13

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:23:18